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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 300, 441, 530, 531, 532, 533, 534, 537, 539,
540, 541, 544, 548, 550, 552, 555, 557, 559, 560, and 561

[Docket No. FSIS-2008-0031]

RIN: 0583-AD36

Mandatory Inspection of Fish of the Order Siluriformes and
Products Derived from Such Fish

AGENCY: Food Safety and Inspection Service.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending its regulations to establish a mandatory inspection program for fish of the order Siluriformes and products derived from these fish. These final regulations implement the provisions of the 2008 and 2014 Farm Bills, which amended the Federal Meat Inspection Act, mandating FSIS inspection of Siluriformes.

DATES: Effective Date: [INSERT DATE 90 DAYS AFTER
PUBLICATION IN THE FEDERAL REGISTER].

On the effective date ([INSERT DATE 90 DAYS AFTER
PUBLICATION IN THE FEDERAL REGISTER]), Siluriformes fish
and fish products are under FSIS jurisdiction. By [INSERT

DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER], foreign countries seeking to continue exporting Siluriformes fish and fish products to the United States during the transitional period are required to submit lists of establishments (with the establishment name and number) that currently export and will continue to export Siluriformes fish and fish products to the United States. Foreign countries are also required to submit documentation showing that they currently have laws or other legal measures in place that provide authority to regulate the growing and processing of fish for human food and to assure compliance with the Food and Drug Administration's (FDA) regulatory requirements in 21 CFR part 123, Fish and Fishery Products.

Transitional Period (transition to complete implementation): Beginning on [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER] and continuing until September 1, 2017, FSIS will conduct inspection and exercise broad enforcement discretion in domestic establishments that slaughter or slaughter and process and distribute Siluriformes fish and fish products. Foreign countries seeking to continue to export Siluriformes fish and fish products to the United States after the

transitional period has expired are required to submit to FSIS by September 1, 2017 adequate documentation showing the equivalence of their Siluriformes inspection systems with that of the United States. Foreign countries submitting such documentation by the deadline are permitted to continue exporting Siluriformes fish and fish products to the United States while FSIS undertakes an evaluation as to equivalency.

Date of Full Enforcement (September 1, 2017): FSIS will fully enforce these regulations in domestic Siluriformes fish products and fish processing establishments. Foreign countries seeking to continue exporting Siluriformes fish and fish products to the United States upon full enforcement are required to submit their documentation showing equivalence by this date.

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SUPPLEMENTARY INFORMATION:

Executive Summary

The 2008 Farm Bill amended the Federal Meat Inspection Act (FMIA), to make "catfish" a species amenable to the FMIA and, therefore, subject to FSIS inspection. In addition, the 2008 Farm Bill gave FSIS the authority to define the term "catfish."

On February 24, 2011, FSIS published a proposed rule that outlined a mandatory catfish inspection program and presented two options for defining "catfish": One option was to define catfish narrowly as those fish belonging to the family Ictaluridae. The other option was a broader definition, all fish of the order Siluriformes (76 FR 10434). FSIS sought public comments on the scope of the definition in the proposed rule. The Agency proposed regulatory requirements for mandatory catfish inspection that were adapted from the meat inspection regulations.

The 2014 Farm Bill, enacted on February 7, 2014, amended the FMIA to remove the term "catfish" and to make "all fish of the order Siluriformes" subject to FSIS jurisdiction and inspection. As a result, FSIS inspection of Siluriformes is mandated by law. This final rule adopts all the regulatory requirements outlined in the February 2011 proposal, with the following changes:

- The term "catfish" defined in proposed 9 CFR part 531 and used throughout the proposed regulatory text, is replaced in this final rule by the term "fish of the order Siluriformes," "Siluriformes fish," or simply "fish," understood to mean, for purposes of the final regulations, any fish of the order Siluriformes.
- The retail store exemption includes, as an exempt retail operation, the slaughter of fish at retail stores or restaurants for consumers who purchase the fish at those facilities, and in accordance with the consumers' request.
- Fish with unusual gross deformities caused by disease or chemical contamination (rather than merely with gross deformities) are not to be used for human food (9 CFR 539.1(d)).
- The labeling regulations (9 CFR 541.7) permit the use of the term "catfish" only on labels of fish classified within the family Ictaluridae, consistent with provisions of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 321d (a) and 343(t)). Fish of the order Siluriformes,

from families other than Ictaluridae, must be labeled with an appropriate common or usual name.

- The labeling regulations (9 CFR 541.7) require packages of Siluriformes fish and fish products that are not ready-to-eat to bear safe-handling instructions to include "fish" in the rationale statement, i.e., "This product was prepared from inspected and passed fish, "and in the labeling statements, i.e., "Keep raw fish from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw fish."
- The labeling regulations (9 CFR 541.7) to clarify that the labeling of fish covered commodities sold by a retailer bear country of origin and method of production information, in compliance with the requirements in 7 CFR part 60, subpart A, Country of Origin Labeling for Fish and Shellfish.
- The import inspection regulations for Siluriformes fish and fish products (9 CFR part

557) to make them consistent with the September 19, 2014, rule amending the FSIS regulations for imported meat, poultry, and egg products (79 FR 56220).

- The regulations include provisions for State-Federal, Federal-State Cooperative Agreements; State Designations (9 CFR part 560) and authorize coordination with States that have fish inspection programs to select certain establishments to participate in an interstate shipment program. These changes reference regulations that took effect after the proposed rule on catfish inspection was published. The regulations incorporate requirements for establishments to maintain written recall plans (9 CFR 532.2) and to notify the FSIS District Office of any adulterated or misbranded product that the establishment has received or shipped in commerce (9 CFR 537.3). These changes reference regulations that took effect after the proposed rule on catfish inspection was published.

- The regulations on official marks and devices for identifying inspected-and-passed fish and fish products (9 CFR 541.2(d)) require whole, gutted fish carcasses to bear the official inspection legend or to be properly packaged in an immediate container marked with the official inspection legend, as well as all other required labeling features.
- The preamble discussion explains that the net weight for ice-glazed fish is determined on a rigid-state basis, as provided in the National Institute of Standards and Technology (NIST) Handbook 133, "Checking the Net Contents of Packaged Goods."
- The regulatory requirements in this final rule will be effective 90 days after its publication. FSIS will implement the regulatory requirements during an 18-month timeframe.
- In addition, during the 18-month transitional period, foreign countries are to begin submitting to FSIS documentation demonstrating

the equivalency of their inspection systems for Siluriformes fish and fish products.

The annualized cost to the Siluriformes fish domestic industry is \$326.55 thousand.¹ This would be an additional annualized average net direct cost to this domestic fish industry of about \$0.0008 per pound of processed Siluriformes fish and Siluriformes products. For comparison, the average price received by domestic processors for domestic catfish (of the order Siluriformes) products was considerably greater at \$3.04 per pound, in 2013. Furthermore, the additional annualized average direct cost to FSIS is \$2,604.4 thousand. On the other hand, the decreased annualized average direct cost to FDA and to the U.S. Department of Commerce's (USDC) National Oceanic and Atmospheric Administration (NOAA)/ National Marine Fisheries Service (NMFS) is \$1,490 thousand because of this final rule. The net difference of these annualized average direct costs to these three Federal government agencies is \$1,114.40 thousand. Therefore, the annualized (at 7 percent) average net direct cost to the Siluriformes fish domestic

¹ Annualized present value of average costs is at a 7 percent discount rate over 10 years.

industry and to the three affected Federal government agencies is \$1,440.95 thousand.

Table 1. Projected Summary Additional Annualized Average Net
Direct Costs (Domestic) of the Final Rule

Affected Sectors of the domestic economy	Additional annualized cost, over 10 years, discounted \$thousands	
	7 percent	3 percent
Siluriformes Fish Industry	\$ 326.55	\$ 317.78
Federal Government Agencies	\$ 1,114.40	\$ 1,097.22
Total	\$ 1,440.95	\$ 1,414.99

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Background

I. 2008 Farm Bill

The Food, Conservation, and Energy Act of 2008 (Pub. L. 110-246, Section 10016(b)), known as the 2008 Farm Bill, amended the Federal Meat Inspection Act (FMIA) to provide that "catfish, as defined by the Secretary," is an

amenable species (21 U.S.C. 601 (w) (2)). Therefore, the 2008 Farm Bill placed catfish and catfish products under FSIS jurisdiction and inspection. The 2008 Farm Bill also added 21 U.S.C. 625, which provides that the sections of the FMIA dealing with ante-mortem and post-mortem inspection and humane slaughter (21 U.S.C. 603 and 604), inspection of carcasses and parts before their entry into establishments or further-processing departments (21 U.S.C. 605), and exemptions from inspection for custom and farm slaughter and processing and other exemptions (21 U.S.C. 623) do not apply to catfish. In addition, the 2008 Farm Bill revised 21 U.S.C. 606, which requires the appointment of inspectors to examine and inspect all meat food products prepared for commerce and provided that the examination and inspection of meat food products derived from catfish are to take into account the conditions under which catfish are raised and transported to processing establishments (21 U.S.C. 606(a) and (b)).

II. 2011 Proposed Rule

On February 24, 2011, FSIS published the proposed rule, "Mandatory Inspection of Catfish and Catfish Products," (76 FR 10434). The regulations proposed to implement the provisions of the 2008 Farm Bill. The

proposed rule's comment period closed on June 24, 2011, 90 days after its publication.

In May 2011, FSIS held two public meetings, in Washington, DC, and Stoneville, MS, to discuss the proposed rule. At those meetings, FSIS provided an overview of the proposed rule and provided the public with an opportunity to comment on the proposed regulation.

Transcripts of the public meeting are available on the FSIS Website at

http://www.fsis.usda.gov/wps/wcm/connect/eefd3e0d-ea69-4c75-b1ac-ea4df9d133e4/Transcripts_05242011_Catfish_meeting.pdf?MOD=AJPERES and

http://www.fsis.usda.gov/wps/wcm/connect/ddb209ab-6aa3-4953-9514-70a8532d3348/Transcripts_05262011_Catfish_meeting.pdf?MOD=AJPERES.

III. 2014 Farm Bill

On February 7, 2014, the Agricultural Act of 2014 (Pub. L. 113-79, Sec. 12106), known as the 2014 Farm Bill, amended Section 1(w) of the FMIA to remove the phrase "catfish, as defined by the Secretary," and replace it with "all fish of the order Siluriformes," thus including

these fish among the amenable species under FSIS jurisdiction and inspection (21 U.S.C. 601(w)(2)). The 2014 Farm Bill also amended the 2008 Farm Bill instructing FSIS, in consultation with the Food and Drug Administration (FDA), to issue final regulations to carry out the amendments in a manner that ensures no duplication in inspection activities. In addition, the 2014 Farm Bill instructed FSIS to execute a Memorandum of Understanding (MOU) with FDA to improve interagency cooperation and to maximize the effectiveness of personnel and resources by ensuring that inspections are not duplicative, and that any information from the examination, testing, and inspections is considered in making risk-based determinations, including the establishment of inspection priorities. The MOU between FSIS and FDA was signed on April 30, 2014, and can be found on the FSIS Website at <http://www.fsis.usda.gov/wps/portal/informational/aboutfsis/food-safety-agencies/mou>.

This final rule issues regulations in response to the 2014 Farm Bill mandate. In addition, this final rule includes a summary of the major issues raised by comments to the 2011 proposed rule and FSIS's responses to the

comments, including changes made to the proposed regulations in response to comments.

IV. Use of the Terms "Catfish" and "Fish" in Preamble Discussion

For purposes of convenience, the preamble discussion in this final rule will use the terms "catfish" and "catfish products" where appropriate when discussing and referencing the 2011 Proposed Rule, since those terms were used in the proposal. The preamble discussion of the final rule amendments will use the terms "fish of the order Siluriformes", "Siluriformes fish," or "fish."

V. Scientific Classification (Taxonomy) of the Catfishes

As discussed in the proposed rule (76 FR 10435), in the taxonomy of the fishes, fish of the order Siluriformes include the Ictaluridae, the North American catfish, to which family belong the fork-tailed channel catfish (Ictalurus punctatus) and blue catfish (I. furcatus), the principal United States farm-raised species, and the flathead catfish (Pylodictis olivaris). Other species in the United States that are in the Ictaluridae family are the white catfish (Ameiurus catus, synonym I. catus), and the black, brown, and yellow bullhead (A. melas, syn. I. melas, A. nebulosus, syn. I. nebulosus, and A. natalis,

syn.I. natalis). Also among the Siluriformes are the air-breathing catfishes of the Clariidae family, to which belongs Clarias fuscus, a species raised in the United States on a small scale in Hawaii.

Another family of Siluriformes, the Pangasiidae, the so-called "giant catfishes,"² includes the aquaculture species basa (Pangasius bocourti) and tra or swai (Pangasius hypophthalmus; syn., Pangasius sutchi), raised principally in Southeast Asia for domestic consumption and export. Other Siluriformes fish species raised in Asia include the hybrid Clarias macrocephalus and North American channel catfish (I. punctatus) that are raised for export to the United States.

VI. Current Inspection of Domestic and Imported Fish

As discussed in the proposed rule, U.S. catfish processors, exporters, and importers have been subject to the U.S. Food and Drug Administration's (FDA) seafood Hazard Analysis Critical Control Point (HACCP) regulations (21 CFR 123) and to other requirements under the Food, Drug, and Cosmetic (FD&C) Act (76 FR 10437). FDA's regulations on current good manufacturing practices

² Integrated Taxonomic Information System (ITIS) report on "Siluriformes." At <http://www.itis.gov>.

(cGMPs, at 21 CFR 110) and on recordkeeping and registration requirements (21 CFR part 1, subparts H and J) also apply to those establishments.

For imported fish and fishery products, FDA requires the importer to either: (1) obtain fish or fish products from a country that has an active memorandum of understanding with FDA that covers the product and documents the equivalence or compliance of the foreign inspection system with that of the United States, or (2) have and implement written verification procedures for ensuring fish and fish products offered for import into the United States were processed in accordance with FDA regulations in 21 CFR part 123 (21 CFR 123.12).

In addition to the FDA regulations, some United States catfish processing establishments contract for voluntary, fee-for-service inspection and certification programs administered by the Department of Commerce's National Marine Fisheries Service (NMFS) under the Agricultural Marketing Act (7 U.S.C. 1622, 1624) and implementing regulations (50 CFR part 260). NMFS administers three levels of seafood inspection programs under authority of the Agricultural Marketing Act (7 U.S.C. 1622, 1624) and regulations implementing that act

(50 CFR part 260). The three levels are: (1) a resident inspection program, which provides inspection to qualifying establishments; (2) an integrated quality assurance program, under which an establishment operates an NMFS-approved quality assurance system and assists NMFS personnel in carrying out U.S. grading or specification regulations; and (3) a HACCP-Quality Management Program (QMP), under which the establishment's quality assurance program is enhanced to meet the ISO 9001 quality management standards.

VII. Public Health Considerations: Potential Chemical and Microbiological Contaminants

As discussed in the proposed rule, because catfish of domestic or foreign origin may be exposed to chemical and microbiological contaminants, FSIS considered the food safety issues that might be presented by catfish in planning its regulatory approach (76 FR 10438).

In the Hazard Identification section of its risk assessment, Assessment of the Potential Change in Human Health Risk Associated with Applying Inspection to Fish of the Order Siluriformes, the Agency discussed the three main classes of chemical residues identified in some domestic and foreign catfish - heavy metals, pesticides,

and antimicrobials and the adverse health effects that have been associated with those chemicals. The assessment also summarized the results of FSIS, Agriculture Marketing Service (AMS) and FDA testing of the fish for these residues (76 FR 10438). The test results showed that, while catfish may not frequently harbor residues of illegal drugs or violative concentrations of other chemicals, the potential exists for such contamination. For example, 9% and 2% of imported catfish tested for malachite green and gentian violet, respectively, tested positive for those banned chemicals. Because some shipments of imported catfish have been found with residues of drugs that FDA has banned and that are unsafe, FSIS proposed to conduct regular residue sampling, as it does for imported meat products, to ensure the safety of imported catfish products (9 CFR 557.6(a)(3)).

For microbial pathogens in catfish, the hazard identification component of the FSIS catfish risk assessment³ identified certain microorganisms as higher-priority. The prioritization was based on association with catfish-related outbreaks and on the severity of

³ U.S. Department of Agriculture. Food Safety and Inspection Service. Office of Public Health Science. December 2010. Draft Risk Assessment of the Potential Human Health Effect of Applying Continuous Inspection to Catfish. Washington, DC (as referenced in the proposed rule).

resultant illness. The microorganisms identified included Salmonella, Listeria monocytogenes, and Enterotoxigenic E. coli (76 FR 10439).

FSIS conducted an assessment of the potential risk to human health from consumption of fish of the order Siluriformes, using the example of Salmonella contamination. The Agency was particularly interested in Salmonella because the bacteria are the most frequently reported cause of foodborne illness in the United States. From a public health perspective, even a small decrease in the percentage of an illness that affects a large number of people can have a substantial effect of decreasing illness, and thus, improve public health. According to the Centers for Disease Control and Prevention (CDC), salmonellosis causes an estimated 1.4 million cases of foodborne illness and more than 400 deaths annually in the United States.⁴ In addition, CDC lists catfish as the vehicle in at least one outbreak of human salmonellosis may have been related to catfish consumption.⁵ Salmonella is a useful model because its presence provides an indication of the sanitary conditions under which food is

⁴ Scallan, et al. Emerging Infectious Diseases, Vol. 17, No. 1. January 2011.

⁵ U.S. Department of Agriculture. Food Safety and Inspection Service. Office of Public Health Science. December 2010. Draft Risk Assessment of the Potential Human Health Effect of Applying Continuous Inspection to Catfish. Washington, D.C. (as referenced in the proposed rule).

produced and, if considering illnesses rather than raw product, the way it is prepared. In addition, an approach that produces a reduction in Salmonella through improved process control can be effective in controlling for the presence of other microbial pathogens.⁶

FSIS invited all interested stakeholders to submit additional data and scientific evidence specific to catfish food safety. USDA also sought public comment on the evidence regarding the public health benefits and cost-effectiveness to be achieved with the proposed program (76 FR 10440). FSIS received comments on these issues and its responses are included in Comments and Responses (Section XI), below.

The FSIS risk assessment has been modified to move the hazard identification section to the body of the risk assessment document. In addition, an Addendum has been added to the risk assessment, which: (1) summarizes potentially relevant research studies published since the draft risk assessment was conducted; (2) provides an update from CDC's outbreak database, stating that it does not indicate that any additional outbreaks have occurred

⁶ Food Safety and Inspection Service. 2006. Review of the Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule pursuant to Section 610 of the Regulatory Flexibility Act, as Amended. Available at: http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2007-0022P/610_Report_PR_HACCP.pdf.

recently; and (3) updates data on the results of analyses of pesticides from the Agricultural Marketing Service's Pesticide Data Program. The updated risk assessment (December 2014) is posted on the FSIS Website at:
<http://www.fsis.usda.gov/wps/wcm/connect/63387be5-ca8e-442d-b047-f031f29a8a47/Silurifomes-RA.pdf?MOD=AJPERES>

VIII. Summary of Proposed and Final Regulatory Requirements

FSIS proposed regulatory requirements for the inspection of catfish and catfish products adapted from the appropriate meat inspection regulations that prevent the transportation, sale, offer for sale or transportation, or receipt for transportation, in commerce, of adulterated or misbranded products (21 U.S.C. 602, 610, 621). Because there are differences between fish and "meat" (cattle, sheep, swine, goats, horses, mules or other equines), FSIS proposed some separate regulations for catfish establishments and products. In many cases, FSIS proposed to reference the existing regulations for meat and meat food products as applying to catfish.

A. Organization of Inspection Operations

In general, the proposed regulations paralleled the sequence of operations from the harvesting and delivery of the fish to the processing plant, through the in-plant operations, to transportation in commerce, specifying export and import requirements where appropriate.

After outlining the district-level supervision of the inspection in proposed 9 CFR 530.2, FSIS made it clear in proposed 9 CFR 530.3, that, as provided in 9 CFR 300.6, persons that are subject to the FMIA, as specifically the catfish inspection provisions, are to grant authorized Agency or Department personnel access to establishments that process catfish and to other establishments in industries related to the catfish processing industry (for example, fish farms, fish hatcheries, fish feed mills, live-fish catchers/loaders and haulers, distributors, and brokers) (76 FR 10440).

FSIS did not make any changes in the final regulations to the inspection operations provisions or to the access Agency or Department personnel have to establishments.

B. Definitions

In proposed 9 CFR part 531, FSIS used the same definitions for the catfish inspection regulations as the meat inspection regulations (9 CFR 301.2). The Agency proposed to add definitions for "catfish," "catfish byproduct," "catfish food product," "catfish product," "farm-raised," and some other terms (76 FR 10441). The ante-mortem inspection, post-mortem inspection, and humane slaughter provisions of the amended FMIA do not apply to catfish, therefore, the Agency did not propose definitions for slaughtering methods. FSIS specifically requested comment on whether the term "slaughter" should be defined.

The Agency received comments on some of the proposed regulatory definitions but, as explained in the Comments and Responses (Section XI) below, determined that it was not necessary to make changes to these definitions. The Agency received numerous comments on the "catfish" species definition. However, as provided by the 2014 Farm Bill, FSIS has jurisdiction over all fish of the order Siluriformes. In this final rule, 9 CFR part 531 has been amended to delete the term "catfish," and its definition, and replace it with "fish," defined as "any fish of the order Siluriformes, whether live or dead."

C. Establishments requiring inspection; grant and approval of inspection

In proposed 9 CFR part 532, FSIS identified the classes of catfish establishments that require inspection and outlined the requirements to qualify for a grant of inspection and the application procedures. FSIS also cross-referenced 9 CFR parts 305 and 306, on the assignment of establishment numbers and the assignment and authorities of FSIS personnel.

As discussed in the proposed rule, the amended FMIA did not provide an exemption from inspection for custom catfish slaughter and processing facilities. FSIS did however, propose to provide an exemption for retail stores and restaurants in proposed 9 CFR 532.3 (under 21 U.S.C. 661(c)(2), that parallels 9 CFR 303.1(d) and (e). FSIS also proposed exemptions for individual household (single-sale) purchases and non-household consumers based on the poultry exemptions in 9 CFR 381.10. FSIS solicited comment on the limits on retail sales to household or non-household consumers.

In proposed 9 CFR 532.4, the Agency asserted Federal pre-emption of State or local authority with respect to premises, facilities, and operations at an official

establishment and with respect to labeling, packaging, and ingredient requirements in proposed 9 CFR 532.4.

In addition, the Agency proposed in 9 CFR 532.5 to exempt from inspection articles that do not contain a minimum amount of catfish (3 percent raw or 2 percent cooked catfish) or are historically not regarded by consumers as products of the catfish food products industry.

FSIS received a comment on the proposed limits on retail sales, discussed in Comments and Responses (Section XI) below. The Agency did not make any changes to the purchase quantity limits in the final regulations. However, in response to a comment on exemptions, the Agency has added language (in 9 CFR 532.3) defining as an exempt retail operation, the slaughter, by the operator of a retail store or restaurant, of live fish purchased by a consumer at the retail store or restaurant for the consumer and at the consumer's instructions.

D. Facility Requirements for Inspection

In proposed 9 CFR part 533, FSIS set forth facility requirements for catfish processing establishments. The regulations proposed requirements for office space and furnishings for program employees, sufficient lighting for

the proper conduct of inspection, facilities for performing inspection, receptacles for diseased carcasses and parts, and materials for cleansing and disinfecting hands, for sterilizing instruments used in handling diseased carcasses, and for cleaning and sanitizing floors and other articles or places contaminated by diseased carcasses. FSIS also proposed that establishments have to provide adequate facilities for the receipt and inspection of catfish and catfish products. The final regulations are consistent with those proposed.

Under this final rule, FSIS will approve operating schedules for fish establishments (9 CFR 533.5) just as it does for official meat establishments. FSIS received comments on schedule of operations and addressed the comments in the Comments and Responses (Section XI), below. The final regulations are consistent with those proposed.

E. Pre-harvest and Transport to Processing Establishment

In proposed 9 CFR part 534, FSIS outlined the pre-harvest standards to be applied to catfish to ensure that the environmental conditions and source waters in which the catfish are grown will not render them unfit for food.

FSIS also proposed general standards for the transportation of catfish to the processing plant. As discussed below, FSIS received comments on pre-harvest and transport issues and is clarifying comments raised in the responses to comments section below. However, the final provisions are consistent with those proposed.

F. Sanitation and Hazard Analysis and Critical Control Point (HACCP) System Requirements for Processing Facilities

In proposed 9 CFR part 537, FSIS proposed to require that any official establishment that prepares or processes catfish or catfish products for human food comply with all of the sanitation requirements in 9 CFR part 416 and the HACCP requirements in 9 CFR part 417. In this final rule, FSIS is adopting 9 CFR part 537, which requires Siluriformes fish establishments to comply with the HACCP and sanitation requirements.

G. Mandatory Dispositions; Performance Standards Respecting Physical, Chemical, or Biological Contaminants

In proposed 9 CFR part 539, FSIS listed the diseases or other conditions that would lead to condemnation of catfish carcasses or parts affected upon inspection. FSIS requested comment on the extent to which infection should

result in condemnation and on whether there are other conditions found in catfish that require such disposition. FSIS received general comments to the effect that diseases should not automatically render catfish adulterated as discussed in Comments and Responses (Section XI) below. FSIS has not changed the proposed regulations in response to these comments. However, in section 539, for greater precision than in the proposed rule, FSIS is stating that "unusual gross deformities caused by disease or chemical contamination" may not be used for human food.

H. Handling and Disposal of Condemned and Inedible Materials

In 9 CFR part 540, FSIS proposed to require that a processor prevent catfish that have died otherwise than by slaughter from entering the official establishment. FSIS explained (in proposed 9 CFR 540.1(b)) that the establishment would have to maintain physical separation between slaughtered catfish and those that died otherwise than by slaughter to prevent commingling of edible and inedible product (76 FR 10444). In addition, FSIS explained that all condemned or otherwise inedible catfish parts would have to be conveyed from the official premises for further disposition at a rendering plant or other

facility that handles inedible products. FSIS received some comments on these requirements, as discussed in Comments and Responses (Section XI) below; however, the Agency did not change the proposed provisions in response to the comments.

I. Marks, Marking, and Labeling of Products and Containers

1. Official Marks and Devices

FSIS proposed to use certain official marks, devices, and certificates for the purpose of identifying inspected and passed catfish and catfish products and their status (9 CFR 541.1 through 541.5).

The Agency proposed in 9 CFR 541.2(a) to provide for an official inspection legend containing the number of the official establishment, and that the form of the official inspection legend will be that for meat products (9 CFR 312.2(b)(1)), or another form that the Agency would prescribe. FSIS requested comments and suggestions on alternative forms. There were no comments on the form of the official inspection legend. Therefore, the Agency is requiring 9 CFR 541.1 that the official inspection legend for fish and fish products be in the form of the meat products inspection legend (9 CFR 312.12) or another form

determined by the Administrator to provide flexibility for future innovations in marking of product.

FSIS proposed to require that whole, gutted catfish carcasses, inspected and passed at an official establishment and intended for sale as whole, gutted catfish, be marked or labeled with the official inspection legend containing the number of the establishment at the time of inspection (9 CFR 541.2(d)). The Agency requested comment on whether the marking is necessary, the form of the mark that would be satisfactory, and how the mark should be applied. FSIS received comments that applying the mark of inspection to all carcasses of whole, gutted fish may be impractical because of the size of the product. As discussed in the Comments and Responses (Section XI) below, the Agency recognizes that it may be impractical to physically apply the inspection legend to whole, gutted fish carcasses. Therefore, in this final rule, 9 CFR 541.2(d) provides that whole, gutted fish carcasses that have been inspected and passed at an official establishment, and that are intended for sale as whole, gutted catfish, must be stamped with the official inspection legend or properly packaged in an immediate

container labeled with the official inspection legend, as well as all other required labeling features.

All other official marks and devices labeling regulations (9 CFR 541.1 through 541.5) are finalized without change.

2. Labeling Requirements; Prior Approval of Labeling

The Agency proposed (9 CFR 541.7) to apply to catfish and catfish products many of the general meat labeling and label approval requirements in 9 CFR part 317, subpart A. The proposed labeling regulations govern labels and labeling, safe-handling labeling, abbreviations of official marks, labeling approval, generically approved labeling, the use of approved labels, the labeling of products for foreign commerce, prohibited practices, the reuse of official inspection marks, filling of containers, relabeling of products, the storage and distribution of labels, and the requirements for packaging materials. In the proposed rule, the Agency specifically noted that processors of catfish and catfish products will be able to use generically approved labeling if it meets the generic labeling requirements in 9 CFR 317.5 (76 FR 10445).

As discussed in the Comments and Responses (Section XI) below, the final provisions in 9 CFR 541.7 include a

paragraph (c), which modifies the safe handling instructions to make the rationale statement read, "This product was prepared from inspected and passed fish," and the labeling statements read, "Keep raw fish from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw fish."

In addition, on November 7, 2013, FSIS published the final rule, "Prior Label Approval System: Generic Label Approval" (78 FR 66826). In that final rule, the Agency consolidated the meat and poultry label approval regulations into a new part, 9 CFR part 412, Label Approval. Therefore, in this final rule, 9 CFR 541.7 includes a paragraph (g) that references 9 CFR 412 for label approval.

This rule adopts the other proposed labeling and label approval regulations in 9 CFR 541.7 without change.

3. Prevention of False or Misleading Labeling Practices

In the preamble of the proposed rule (76 FR 10445), FSIS explained that under its regulations, no product or any of its wrappers, packaging, or other containers may bear any false or misleading marking, label, or other labeling, and no statement, work picture, design, or

device that conveys any false impression or gives any false indication of origin or quality or that is otherwise false or misleading may appear in any marking or other labeling. In addition, no product may be enclosed wholly or partly in any wrapper, packaging, or other container that is made, formed, or filled in a manner that would make it misleading (9 CFR 317.8).

The Agency explained that to prevent the misuse of labeling, FSIS enforces regulations controlling the conditions under which product may be relabeled at a location other than an official establishment (9 CFR 317.12). The Agency also regulates the conditions under which labels, wrappers, or containers bearing official marks may be transported from one official establishment to another official establishment (9 CFR 317.13). FSIS proposed that all these requirements, which apply to meat and meat food products, would apply to catfish and catfish products under the proposed rule (9 CFR 541.7(a)).

In the preamble discussion on preventing false or misleading labeling practices, the Agency stated that, after a fish is processed, it is a major challenge for regulators and industry to visually identify the species of fish (76 FR 10445). Because of the interest of the

catfish products industry and consumers in ensuring that product labeling correctly represents the actual species of fish in the product, FSIS was considering various technological means to verify catfish species. The Agency requested comment and suggestions on species verification methods that the Agency might use.

The Agency received several comments on the methods of speciation and country of origin labeling. The responses to these comments are discussed in the Comments and Responses (Section XI) below. This rule finalizes the prevention of false or misleading labeling regulations in 9 CFR 541.7(a) (consistent with 9 CFR 317.8, 317.12, and 317.13 specifically) and adds 9 CFR 541.7(b) to correct the reference to the AMS regulations for the country of origin labeling for fish (7 CFR, part 60, subpart A).

In addition, under the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 321d (a)), the term "catfish" may only be considered to be a common or usual name (or part thereof) for fish classified within the family Ictaluridae; and only labeling or advertising for fish classified within that family may include the term "catfish." Also, a food is misbranded if it purports to be or is represented as catfish, unless it is fish

classified within the family Ictaluridae (21 U.S.C. 343(t)). Therefore, in this final rule, FSIS has revised proposed 9 CFR 541.7 to require that the term "catfish" be used only on labels and in labeling of fish within the family Ictaluridae and the products of those fish.

The Agency is also requiring in 9 CFR 541.7 that fish and fish products in all other families in the order Siluriformes be labeled with appropriate common or usual names. Domestic and foreign fish establishments should consult FDA's "Guidance for Industry: The Seafood List - FDA's Guide to Acceptable Market Names for Seafood Sold in Interstate Commerce," for appropriate common or usual names

(<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/seafood/ucm113260.htm>).

4. Net Weight and Retained Water

As discussed in the preamble, FSIS's labeling regulations on net weight of meat products incorporates by reference the National Institute of Standards and Technology's (NIST) Handbook 133 (76 FR 10445). The Agency also explained that the net weight of catfish presents a specific challenge because of the frequent and varying use of ice-glazing to preserve the freshness of

the product (76 FR 10445). The Agency proposed that packages of fresh or fresh-frozen catfish or parts must be labeled to reflect 100-percent net weight after thawing (9 CFR 541.7(b)(1)).

To regulate the net weight for raw catfish products, FSIS proposed in 9 CFR 541.7(b) to apply the requirements for control of retained water from processing in raw meat and poultry products through 9 CFR part 441. Retained water - water remaining in raw product after it undergoes immersion chilling or a similar process - would not be permitted unless the official establishment could show that the retained water is an unavoidable consequence of the process (9 CFR 441.10(a)). The establishment would have to label its product to state the maximum percentage of retained water.

In response to comment, discussed further in Comments and Responses (Section XI) below, the Agency is clarifying that, according to NIST Handbook 133 net weight test procedures for ice-glazed fish products are "deglaed" by placing the product under a gentle spray of cold water, and the product should remain rigid. However, as proposed, the NIST Handbook 133, net weight test procedures for frozen or fresh-frozen fish are determined

on a thawed basis. The proposed net weight and retained water labeling regulations in 9 CFR 541.7 are adopted without change.

5. Nutrition Labeling Requirements

In 9 CFR 541.7(c), the Agency proposed, under the FMIA (21 U.S.C. 601(n)(1), 621) to apply the nutrition labeling requirements to catfish and catfish products that are not raw, single-ingredient products. The Agency received no comments on this provision, and it is adopted as proposed.

J. Food Ingredients Permitted

FSIS proposed in 9 CFR part 544 to apply to catfish products the requirements in 9 CFR part 424 prohibiting a product from bearing or containing any food ingredient that would render it adulterated or misbranded.

As discussed in the proposed rule, FSIS will make determinations on the safety and suitability of uses of food ingredients for Siluriformes products in consultation with FDA, as it does for all food ingredients (76 FR 10446). FSIS compiles safe and suitable uses, including limits and conditions of use, of food ingredients in these products and makes the information available in an instruction to its inspection force in FSIS Directive

7120.1. This directive is regularly updated and published on the Agency's Website at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/directives/7000-series>. This final rule adopts the requirement as proposed.

K. Ready-to-eat and Canned Fish Products: Control of *Listeria monocytogenes*

As discussed in the proposed rule (76 FR 10446), ready-to-eat (RTE) catfish products, such as smoked catfish, would have to comply with appropriate performance standards if they are not to be considered adulterated under the FMIA (21 U.S.C. 601(m)). FSIS proposed to make post-lethality-exposed catfish products subject to the requirements in 9 CFR part 430 (proposed 9 CFR 548.6). An RTE catfish product would be considered adulterated if it contains *L. monocytogenes*, or if it comes into direct contact with a food-contact surface that is contaminated with *L. monocytogenes* because it is likely to be consumed without further processing, such as cooking. The Agency is adopting this provision as proposed.

L. Canned Products

As discussed in the proposed rule, FSIS is not aware of any canned catfish products processed in the U.S., but

canned catfish soups are imported into this country (76 FR 10446). FSIS proposed (9 CFR 548.6) that any domestic canned catfish products that an official establishment manufactures will be subject to requirements similar to those for canning and canned meat products (9 CFR 318.300-318.311). As explained in the proposed rule, imported canned catfish products would have to be prepared under requirements that are equivalent to those applying to domestic products. FSIS is adopting this provision as proposed.

M. Accredited Laboratories

FSIS proposed that catfish processing establishments, like other official establishments, may use a non-Federal analytical laboratory that meets the accreditation requirements in 9 CFR 439 instead of an FSIS laboratory to analyze official regulatory samples (proposed 9 CFR 548.9). The Agency is adopting proposed 9 CFR 548.9 as final, without changes.

N. Standards of Identity and Composition

In the preamble to the proposed rule, FSIS requested comment on whether the Agency should promulgate any standards of identity or composition for catfish products (76 FR 10446). The Agency received comments on catfish

standards of identity, as discussed in Comments and Responses (Section XI) below, but is not promulgating standards of identity or composition in this final rule.

O. Exports

The Agency proposed (9 CFR part 552) to adopt requirements for exported catfish and catfish products that are similar to those that apply to meat articles by cross-referencing the provision of 9 CFR part 322. There are no changes to the proposed regulations in this final rule.

P. Transportation in Commerce

FSIS proposed in 9 CFR 555.1 to require that any catfish product capable of use as human food that is to be transported in commerce be properly handled and maintained to ensure that it is not adulterated and is properly marked and labeled. As discussed in the proposed rule, a transport conveyance intended to carry catfish products would be subject to FSIS inspection to determine its sanitary condition (76 FR 10447). FSIS also explained that products on an insanitary vehicle would have to be removed and either handled in accordance with the regulations on mandatory dispositions or on the handling

of condemned and inedible materials (9 CFR part 539 or part 540).

The Agency also discussed that it had tentatively determined that other regulations on the transportation of meat and meat food products (in 9 CFR part 325) are appropriate for the transportation of catfish products (9 CFR 555.3-555.8). The proposed regulations addressed the transportation of unmarked inspected product under FSIS affixed-seal; product that may have become adulterated in transit or storage; inedible products; the filing of original certificates for unmarked inspected products; and the unloading of any catfish product from an officially sealed conveyance or loading after the conveyance has left the official establishment. The Agency is adopting these proposed regulations as final.

Q. Imported Products

As FSIS discussed in the proposed rule, under the FMIA, the provisions of the act governing imports apply to catfish and catfish products (76 FR 10447). FSIS proposed to apply the requirements for the inspection of imported meat products to imported catfish products (9 CFR part 557, referencing 9 CFR part 327). Under the proposed rule and final rule, FSIS would have to find that the system of

fish inspection maintained by any foreign country, with respect to establishments preparing products in such country for export to the United States, insures compliance of the establishments and their products with requirements equivalent to the inspection and other requirements of the FMIA and the regulations that implement it in the United States. When the Agency determines that a foreign country's inspection system for fish is equivalent to that operated by FSIS, the Agency would publish a proposed rule to list the country in the regulations as eligible to export Siluriformes fish and fish products to the U.S., and would provide an opportunity for public comment. Should the Agency decide to list the country's system as equivalent, FSIS would respond to comments in the final rule and list the name of the country in the regulations (9 CFR 557.2(b)). FSIS is adopting these proposed requirements as final, except for terminology changes to reflect that they apply to fish in the order Siluriformes.

On September 19, 2014, FSIS published a final rule (79 FR 56220) amending its regulations for imported meat, poultry, and egg products to provide, among other things, for use of the Agency's electronic Public Health

Information System (PHIS) import component. In addition to providing for the PHIS import component, the final rule deleted overly prescriptive formatting and narrative requirements for foreign establishments and inspection certificates, required additional information on the certificates, and made the requirements the same for imported meat, poultry, and egg products. The regulations in 9 CFR part 557 adopted by this final rule on Siluriformes inspection reflect the amendments to accommodate the use of PHIS.

R. Demonstrating Equivalence of Foreign Systems

FSIS proposed that countries will need to demonstrate that their inspection systems are equivalent to the U.S. system in the following respects:

(1) Program administration. Under proposed 9 CFR 557.2 (referencing 9 CFR 327.2) the foreign program for catfish would have to be staffed in a way that will ensure uniform enforcement of the laws and regulations. Ultimate control and supervision must rest with the national government (9 CFR 327.2(a)(2)(i)(B)). Qualified, competent inspection personnel must be employed in the food safety system (9 CFR 327.2(a)(2)(i)(C)). National inspection officials would have to have the authority to

enforce requisite laws and regulations and certify or refuse to certify products intended for export (9 CFR 327.2(a)(2)(i)(D)). There would have to be adequate administrative and technical support and inspection, sanitation, quality, species verification, residue standards, and other regulatory requirements that are equivalent to those of the United States (9 CFR 327.2(a)(2)(i)(E)-(G)). FSIS is adopting these requirements as proposed.

(2) Legal authority and requirements governing catfish and catfish products inspection. Under proposed 9 CFR 557.3, to be considered eligible to export catfish products to the United States, foreign countries would have to enforce laws and regulations that address the conditions under which catfish are raised and transported to the processing establishment (9 CFR 327.2(a)(2)(ii)(I)). In countries where catfish producers use floating cages on rivers and "raceway ponds" that are filled and emptied by the continuous flow of water from nearby rivers, under the proposed rule, the water quality, residue, and other standards would have to be equivalent to those applying to catfish raised in the United States.

Also, under the proposed rule, eligible foreign countries would have to establish standards for, and maintain official supervision of, preparation and processing of product to ensure that adulterated or misbranded product is not prepared for export to the United States (9 CFR 327.2(a)(ii)(D)). A single standard of inspection and sanitation would need to be maintained throughout all certified establishments (9 CFR 327.2(a)(ii)(E)). The country's requirements would need to address sanitary handling of product and provide for official controls over condemned material; a HACCP system equivalent to that set forth in 9 CFR part 417; and other applicable controls under the FMIA or implementing regulations (9 CFR 327.2(a)(ii)(F)-(I)).

(3) Document evaluation and system review. Under the proposed rule, foreign countries seeking eligibility to export catfish and catfish products into the United States (9 CFR 557.2(a)) would also have to present to FSIS copies of laws, regulations, and other information pertaining to their system of catfish product inspection, just as countries now do when they seek eligibility to export products of other species amenable to the FMIA. FSIS estimates that it would take approximately 3 months

per submission to evaluate this documentation. FSIS would determine eligibility on the basis of a study of these documents and an on-site visit to the country of the system in operation by FSIS. FSIS would also conduct periodic reviews of foreign catfish products inspection systems to determine their continued eligibility (9 CFR 327.2(a)(3)).

(4) Maintenance of standards. In addition, countries that FSIS eventually determines to be eligible to export catfish and catfish products into the United States would have to provide for periodic visits to certified establishments to ensure that U.S. requirements are being met and for written reports on the supervisory visits (proposed 9 CFR 557.2, under 21 U.S.C. 620). The reports would have to be available to FSIS. The foreign program would have to conduct random sampling of catfish tissues and the testing of the tissues for residues identified by FSIS or by the foreign inspection authority as potential contaminants, in accordance with sampling and analytical techniques approved by FSIS (9 CFR 327.2(a)(2)(iv)(C)). The residue testing would have to be conducted on samples from catfish intended for export to the United States.

Once FSIS has determined that countries maintain equivalent inspection systems, only certified foreign catfish establishments, that is, establishments that foreign program officials have certified as complying with the requirements equivalent to United States requirements, would be eligible to export their catfish products to the United States. If FSIS found that a foreign establishment is not in compliance with United States requirements for imported products, FSIS would terminate the eligibility of the establishment. FSIS would provide reasonable notice to the foreign government of the proposed termination of eligibility, unless delay in notification could result in the importation of adulterated or misbranded product (9 CFR 327.2(a)(3)).

This final rule adopts these proposed regulations without change. However, to provide foreign countries with adequate time to transition to the final regulations, on the date that the rule becomes effective, [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER], foreign countries seeking to continue exporting Siluriformes fish and fish products to the United States during the 18-month transitional period are permitted to do so, provided they submit 1) the list of establishments

(with the establishment name and number) currently exporting Siluriformes fish and fish products to the United States and 2) adequate documentation demonstrating that the foreign country currently has laws or other legal measures in place that provide authority to regulate the growing and processing of fish for human food and to assure compliance with the Food and Drug Administration's (FDA) regulatory requirements in 21 CFR part 123, Fish and Fishery Products, which include requirements for good manufacturing practices, Hazard analysis and Hazard Analysis Critical Control Point (HACCP) plans, and sanitation control procedures. This initial documentation will not be used to establish equivalency.

By the end of the 18-month transitional period, foreign countries seeking equivalency must submit documentation showing that they have systems for inspection of Siluriformes fish and fish products equivalent to FSIS's system. A country can continue to export fish products to the United States after the 18-month transitional period, if the country has submitted its documentation on equivalency by the start of full enforcement of this rule, September 1, 2017. See Section XII., "FSIS Implementation," for more details.

S. Marking and Labeling of Imported Products

The proposed regulations (9 CFR 557.14 and 557.15) reference the meat regulations (9 CFR 327.14 and 327.15) requiring the marking and labeling of immediate and outside containers of imported catfish and catfish products. There are no changes to these proposed regulations in this final rule.

IX. Proposed Regulations Under Other FMIA Subchapters

A. Rules of Practice; Reference to Rules of Practice

FSIS proposed to apply its rules of practice (9 CFR part 500) in enforcing the proposed catfish inspection regulations (proposed 9 CFR 561.1). Also, FSIS proposed to provide establishments with an opportunity for presentation of views (proposed 9 CFR 561.2, referencing 9 CFR part 335) before reporting violations to the Department of Justice for criminal prosecution. The procedure to be followed in a case relating to catfish and catfish products inspection would be the same as that followed in a case relating to meat and meat food products inspection. FSIS uses its rules of practice for enforcement processes that may lead to such actions as withholding (refusing to allow the mark of inspection to be applied to product) or suspension (withdrawing

inspection program employees from a facility) of inspection. There are no changes to the proposed regulations in this final rule.

B. Detention, and Seizure and Condemnation

1. Detention.

FSIS proposed to exercise its detention authority under the FMIA upon finding that catfish or catfish products in commerce are adulterated, misbranded, or otherwise in violation of the Act or regulatory requirements (proposed 9 CFR 559.1, referencing 9 CFR 329.1-329.6). This final rule adopts these proposed regulations without change.

2. Seizure and Condemnation

FSIS proposed to apply the provisions for seizure and condemnation in the meat regulations (9 CFR 329.7-329.9) to catfish (proposed 9 CFR 559.2). The regulations also address criminal offenses addressed in Sections 22 and 405 of the FMIA (21 U.S.C. 622, 675), such as bribery of Program employees, receipt of gifts by Program employees, and assaults on, or other interference with, Program employees while engaged in, or on account of, the performance of their official duties under the Act. There

are no changes to the proposed regulations in this final rule.

X. Records Required To Be Kept

In proposed 9 CFR part 550, FSIS proposed to require persons and firms involved in processing, buying and selling, or rendering catfish or catfish products to keep records on their activities respecting catfish sold, transported, or offered for sale or transport, in commerce. The records they would be required to keep include sales records or invoices, shippers' certificates and required permits, records of seal numbers used in the sealed transport of inedible products, guaranties provided by suppliers of packaging materials, canning records as required by 9 CFR part 318, subpart G, nutrition labeling records, and records of all labeling, along with the formulation and processing procedures. In addition, the Agency proposed that persons and firms covered by the recordkeeping requirements would have to register with the FSIS Administrator, and asked for comment on a proposed time frame for completing this registration (76 FR 10449).

FSIS also stated that it would require each official establishment to provide accurate information to FSIS employees so that they could report on the amount of

products prepared or handled in the establishment, and on sanitation, microbiological testing, and other aspects of the establishment's operations (76 FR 10449). The Agency proposed that the operator of each establishment report quarterly on the number of pounds of catfish processed. The report has to be filed within 15 days after the end of each quarter. The establishment operator would also have to file other reports as FSIS might require from time to time under the FMIA (9 CFR 550.6).

In addition, FSIS proposed to require that a consignee who refuses to accept delivery of a product bearing the mark of inspection because it is adulterated or misbranded notify the Inspector-in-Charge of the kind, quantity, source, and present location of the product (9 CFR 550.7).

There are no changes to the proposed regulations in this final rule.

XI. Comments and Responses

FSIS received approximately 4,335 comments on the proposed rule. About 4,000 of the comments were form letters submitted as part of a write-in campaign initiated by a consumer advocacy organization. FSIS also received a separate petition signed by 41 private citizens, and a

joint submission from 16 food and agricultural organizations and companies. Almost all of the remaining comments were from private citizens; domestic and foreign catfish farmers; trade groups and associations representing the catfish and seafood industry (processing, manufacturing, storage, and distribution); the catfish processing industry; consumer advocacy groups; members of U.S. Congress; foreign government ministries of agriculture and rural development; foreign chambers of commerce; trade associations representing retail and restaurant industries; aquaculture industry advocacy associations; public policy organizations; U.S. State and county officials; aquaculture scientists; members of academia; restaurant consortiums; a foreign government; an organization of U.S. regulatory officials; and a small business advocacy association. The Agency's responses to comments on major issues concerning the proposed rule are discussed below.

A. General Opposition

Comment: Some comments opposed the transfer of jurisdiction over catfish and catfish products to FSIS for a variety of reasons. The comments generally expressed the concern that the proposal was unnecessary, wasteful,

unjustified, or redundant. Several commenters stated that both FDA and FSIS will regulate the same product. Many commenters also stated that FDA's current regulatory approach ensures the safety of domestically produced and imported seafood products, and that the catfish industry has a demonstrated track record of food safety.

Response: Under the 2008 Farm Bill, FSIS was required to develop regulations, in consultation with FDA, to implement FSIS inspection of "catfish," as defined by its regulations. Under the 2014 Farm Bill, which amended the 2008 Farm Bill, all fish of the order Siluriformes are amenable species under the jurisdiction of FSIS. The 2014 Farm Bill requires FSIS to develop final regulations in consultation with FDA. FSIS consulted FDA during development of these final regulations. The legislation also requires FSIS and FDA to execute a Memorandum of Understanding (MOU) to improve interagency cooperation on food safety and fraud prevention and to maximize the effectiveness of limited personnel and resources. FDA and FSIS have agreed on this MOU. It is posted at <http://www.fsis.usda.gov/wps/portal/informational/aboutfsis/food-safety-agencies/mou>.

B. The Definition of Catfish

Comments: Many comments representing domestic groups, individuals, and numerous comments from members of the U.S. Congress, urged FSIS to define catfish as all species in the order Siluriformes, the broader definition. The commenters stated that the broader definition affords the greatest food safety protection for the entire "catfish" category of seafood; it is consistent with the science of taxonomy; and it would include all imported catfish.

Foreign governments, foreign ministries of agriculture, foreign catfish farmers, and foreign industries supported defining catfish as only fish of the Ictaluridae family, stating that this definition is the current FDA regulatory definition, adopted by Congress in the 2002 Farm Bill (21 U.S.C. 321d (a)), and that it would provide consistency and eliminate confusion among seafood exporters.

Response: The 2014 Farm Bill settled this issue. It amended the FMIA to give FSIS jurisdiction over all establishments that slaughter or process "all fish of the order Siluriformes." Many Siluriformes fish species are produced in foreign countries and are exported to the United States. To be eligible to be imported into the

U.S., these products will have to be produced under inspection systems equivalent to the U.S. system and will be subject to reinspection in the U.S.

For labeling or advertising purposes, the FD&C Act provides that the term "catfish" can only be used in labeling of fish classified within the family Ictaluridae. By removing the term "catfish" from the FMIA and using the term "certain fish" in its stead, Congress left FSIS free to use the FD&C Act's definition of "catfish." Therefore, in this final rule, FSIS is modifying the labeling regulations that it proposed to permit the use of the term "catfish" only on labels of fish from the Ictaluridae family. Siluriformes fish, which includes families in addition to Ictaluridae, will need to be labeled with the appropriate common or usual name.

C. Risk Assessment

Comments: Many comments asked for additional evidence to support the shift in jurisdiction for catfish and catfish products from FDA to FSIS. The comments also stated that the products of aquaculture are rarely involved in outbreaks of salmonellosis. Comments from a foreign government, a foreign country's chamber of commerce, members of the seafood industry, and trade

policy organizations asked FSIS to explain how the proposed rule was consistent with its World Trade Organization's (WTO) Sanitary and Phytosanitary Measures (the "SPS Agreement") obligations. A domestic catfish processor expressed the need for a risk assessment associated with chemical contamination of catfish aquaculture based on the constantly changing quality of river water.

Response: It is important to note that the risk assessment was not conducted "to support the shift in jurisdiction for catfish and catfish products from FDA to FSIS." FSIS conducted a quantitative food safety risk assessment, in accordance with national and international guidelines, that included all four components of a standard risk assessment: (1) Hazard Identification, (2) Exposure Assessment, (3) Hazard Characterization, and (4) Risk Characterization. FSIS thoroughly reviewed the scientific literature and garnered input from scientists from other Federal agencies and academia in performing the Hazard Identification portion of the risk assessment. The risk assessment was also independently peer-reviewed in accordance with the Office of Management and Budget's Peer Review Guidelines, as required under the Information

Quality Act (Pub. L. No. 106-554). The purpose of the risk assessment was to provide predictions of the public health benefits (e.g., reduction in foodborne illnesses) that might accompany the implementation of a mandatory inspection system. The risk assessment identified Salmonella as a hazard of primary concern because: (1) it is the foodborne pathogen associated with catfish (McCoy et. al., Journal of Food Protection 74(3):500-16, 2011); (2) there was more available data for assessing the risk of human illnesses associated with Salmonella and assessing the effectiveness of an FSIS regulatory strategy for this hazard; (3) its occurrence in domestic catfish processing facilities and retail catfish is documented; (4) its presence in catfish imported to the United States is documented; and (5) CDC identifies catfish as the vehicle associated with a 1991 outbreak of Salmonella hadar.

The estimates for human salmonellosis cases associated with catfish consumed in the United States (under current inspection programs) were supported by an FSIS Risk Assessment and Analytics Staff independent analysis ("attribution analysis") on the basis of

epidemiological data.^{7,8} The Centers for Disease Control and Prevention (CDC) concurred with FSIS' findings and stated that FSIS may even have underestimated the number of human salmonellosis cases attributed to catfish by not considering outbreaks attributed to "finfish," that may have been "catfish."

FSIS requirements are consistent with the WTO SPS Agreement on the Application of Sanitary and Phytosanitary Measures. Under the articles of the SPS Agreement, a measure can be taken when it is necessary to protect against a public health hazard and there is scientific support for the measure.

Chemical contamination hazards are important to catfish food safety and FSIS anticipates generating chemical contamination data once it begins its inspection program. Any risks identified through FSIS's surveillance will be addressed to ensure food safety.

D. Cost and Benefits Analysis

Comments: Several comments questioned FSIS's "break-even" analysis in light of the fact that, historically, so

⁷ U.S. Centers for Disease Control and Prevention (CDC). (June 2009) Foodborne Disease Outbreak Surveillance Data. Atlanta, GA. Retrieved from <http://www.cdc.gov/foodsafety/fdoss/index.html>

⁸ Mead, P.S., Slutsker, L., Dietz, V., McCaig, L.F., Bresee, J.S., Shapiro, C., Griffin, P.M., & Tauxe, R.V. (1999). Food-Related Illness and Death in the United States. *Emerging Infectious Diseases*, 5, 607-625.

few salmonellosis illnesses have been associated with the consumption of contaminated catfish. A member of academia, however, stated that the benefits of implementing this rule would be far greater than those estimated because the calculations did not include the long-term public health benefits of preventing imported product contaminated with chemical residues, such as malachite green, from entering the United States. Other comments stated that the incremental cost increases associated with the rule would negatively affect the marketability of catfish and catfish products.

Response: By focusing solely on Salmonella in the risk assessment and the subsequent break-even analysis, FSIS took a conservative approach to estimating the number of illnesses prevented needed to offset costs of implementing this rule. It is possible that the process steps needed to reduce Salmonella on fish will also result in the reduction of other pathogenic microorganisms, such as E. coli (enterohemorrhagic, Shigatoxigenic, enterotoxigenic, and enteropathogenic strains), Listeria monocytogenes, and Clostridium botulinum on raw and ready-to-eat (RTE) fish.

Comment: Several comments questioned FSIS's relatively high Agency cost to implement and maintain the proposed mandatory catfish inspection program.

Response: In the final rule costs analysis, FSIS lowered its estimated additional net direct costs to implement and continue the mandatory inspection of fish and fish products. These costs are lower than preliminary Regulatory Impact Analysis (RIA) estimates because the domestic fish industry is now more consolidated, contracted, and concentrated and will require fewer additional FSIS resources for inspection. Furthermore, the FSIS Office of Field Operations was recently consolidated and now we will use more of the existing OFO staff (with minimal new hires and relocations) in patrol assignments for the processing-only establishments. This recent consolidation transitioned the Office of Catfish Inspection Programs (OCIP) to OFO. Thus, this transition would eliminate permanent staff positions (such as for managers, supervisors, inspection program personnel, and technical staff) that would have been dedicated to the OCIP, as discussed in the PRIA (scenario 1) of the published Proposed Rule. The Agency cost estimate is in

the full RIA of the final rule, in the Appendix material (FRIA Appendix A).

Comment: A domestic catfish processor claimed that transferring catfish inspection to FSIS would give processors of all other non-FSIS inspected seafood an unfair cost advantage.

Response: FSIS projects in its regulatory impact analysis that the final rule would increase domestic product average net direct cost of aggregate processed fish and fish food products by \$0.0008 per pound. According to the USDA, National Agricultural Statistics Service (NASS), the average price received by domestic processors for domestic catfish products was \$3.04 per pound in 2013. Thus, FSIS's projected additional net direct cost to the domestic fish processing industry is relatively small when compared to the average domestic price received.

Comment: A domestic catfish processor claimed that transferring catfish inspection to FSIS would increase catfish processor's costs. The processor stated that the initial cost to house inspectors and for the industry to conduct laboratory analysis sufficiently rigorous to ensure compliance with FSIS requirements may be

significant. In addition, the processor stated that the testing for drugs with sufficient rigor would likely cost several thousand dollars per year.

Response: FSIS projected an additional average net direct cost of \$0.0008 per pound of aggregated processed fish and fish products to the domestic processors. This additional average net direct cost includes expected capital costs including additional office space for inspectors. Furthermore, the Agency projected additional establishment testing costs for required validation and verification of HACCP processing plans at official establishments. FSIS found on site visits that many domestic processors already have available office space for inspectors. Furthermore, many of these domestic processors already test their fish and fish products for microorganisms and drugs, according to the FDA 2011 Report. Thus, some domestic processors would have little to no additional costs for inspector office space or for microbe and drug testing. The aggregate direct cost FSIS projects for the domestic activities is an annualized \$326.55 thousand.⁹

⁹ Annualized present value of average costs is at a 7 percent discount rate over 10 years.

Comment: A domestic seafood distributor stated that the proposed rule regulatory impact analysis underestimated the number of catfish processors in the U.S. A public policy organization stated that the data presented in the regulatory impact analysis were not properly attributed to a source, that no specific market failure or major health problem was identified, and that the theory behind the assertions was not articulated. The commenter further added that the regulatory impact analysis calculates a salmonellosis illness baseline without considering whether poultry processors used voluntary (fee-for-service) inspection services at the time, and that the numbers cannot be compared to the catfish industry.

Response: The commenter provided no estimate of the number of affected catfish processors in the United States. In the proposed rule, FSIS used data from its research and site visits to project the number of affected domestic processors and distributors. The proposed rule regulatory impact analysis (RIA) data sources are in footnotes, tables, a list of references, and exhibits. In the final rule analysis, FSIS used the best available data from the Food and Drug Administration (FDA); National

Oceanic and Atmospheric Administration (NOAA)/National Marine Fisheries Service (NMFS); import records of the U.S. Department of Homeland Security (DHS/CBP); and Dun and Bradstreet, and updated the presentation of summary data and its sources.

As for the market failure, FSIS finds foodborne illness to be potentially consistent with an informational market failure; specifically, the market for food may be characterized by an asymmetry in which producers know more than consumers about the microbiologic status and chemical residue status of the foods they prepare and consume.

While the proposed rule employed a risk assessment in its PRIA, the final rule employs a break-even analysis in its RIA. The break-even analysis was calculated using catfish data and did not incorporate findings from the risk assessment.

Comment: A trade association stated that the proposed rule would deprive seafood processors of imported products that they need and would subject them to duplicative and costly regulation.

Response: The 2014 Farm Bill amendments of the FMIA give FSIS jurisdiction over all Siluriformes fish and fish products, including Siluriformes fish and fish products

imported from other countries. Through its planned outreach to affected entities, FSIS will address the continued importation of those fish species and will conduct records reviews and audits to verify that all countries that import those fish species to the U.S. maintain inspections systems and requirements that are equivalent to those of FSIS. See sections Q. Imported Products and R. Demonstrating Equivalence of Foreign Systems for additional discussion of how FSIS will evaluate the equivalence of these countries and conduct rulemaking to list these countries in the regulations.

To prevent duplicative and costly regulation, the 2014 Farm Bill also instructed FSIS to execute a MOU with FDA to maximize the effectiveness of limited personnel and by ensuring that inspections of shipments and processing facilities are not duplicative, and that any information resulting from examination, testing, and inspections is considered in making risk-based determinations, including the establishment of inspection priorities.

E. Trade Barriers and Agreements

Comments: A comment stated that the proposed rule violated the World Trade Organization (WTO) National Treatment Principle, which states that imported and

locally-produced goods should be treated equally once they enter the market. Another comment stated that the proposal violated the WTO agreement on Technical Barriers to Trade because it may be considered a disguised restriction on international trade. Some comments stated that the United States could be subjected to WTO-sanctioned tariffs if the rule is found by the WTO dispute settlement body to be noncompliant with its WTO obligations. A comment from a foreign government stated that it had been exporting catfish to the U.S. for many years under a food and feed safety agreement protocol with FDA, and that it hoped that the protocol would continue.

Response: As with all other products FSIS regulates under the FMIA, this final rule would ensure that equivalent regulatory standards are applied to imported and domestic fish of the order Siluriformes. Therefore, this rule is not a violation of WTO National Treatment Principles. Imported products must be produced under an inspection system equivalent to the domestic system.

F. Equivalency and Implementation

Comment: Many domestic catfish farmers and processors and private citizens endorsed the concept of an exporting country's food safety system being held to

equivalent standards that are applied to domestic production. A trade association strongly opposed phasing in the requirements because the phase-in jeopardizes the health and safety of consumers and is unnecessary because there has been ample time to comply. An aquaculture industry advocacy association stated that no catfish imports should enter the United States until the foreign system overseeing them is determined to be equivalent. The same association and a member of academia stated that requirements for domestic and foreign entities should have the same effective date. A foreign agricultural ministry requested that FSIS commit to a timeframe for equivalence determinations. Some commenters recommended possible timeframes for implementation.

Response: The Agency has given the implementation of this final rule careful consideration and has outlined the Agency's implementation strategy in Section XII. Under this implementation plan, FSIS will begin implementing inspection of domestic Siluriformes producers and inspection of imported Siluriformes product at the same time, 90 days after the publication of this final rule. Siluriformes fish and fish products exported to the U.S. will be subject to species and residue testing. Also, at

the start of implementation, 90 days after the publication of this final rule, foreign countries will have to submit written documentation identifying a list of establishments (with the establishment name and number) that currently export and will continue to export Siluriformes fish and Siluriformes fish products to the U.S., and demonstrating that they have laws or other legal measures in place that provide authority to regulate the growing and processing of fish for human food and to assure compliance with FDA's regulatory requirements. In addition, during the 18-month transitional period, foreign countries seeking to continue importing into the United States Siluriformes and products derived from these fish after the expiration of the transitional period are encouraged to start submitting their documentation demonstrating the equivalency of their Siluriformes fish and fish products inspection systems. In any event, such documentation must be submitted by the end of the transitional period.

G. Facilities Requirements and Schedule of Operations

Comment: A domestic seafood processor stated that the proposed requirement (9 CFR 533.1) for separation of inspected and non-inspected facilities would make it

impossible for them to operate because of a lack of space, resulting in huge hardship.

Response: Consistent with meat regulations in 9 CFR 305.2(a), FSIS generally considers a separation in time or space between inspected and non-inspected facilities to be sufficient, under certain conditions, to meet the requirement for separation of facilities. Therefore, common areas for inspected and uninspected operations may be used if the inspected product is acceptably maintained and protected to prevent product adulteration.

Comment: A trade association suggested that the proposed phrase "docks and receiving room" (9 CFR 533.4(f)) be replaced with "existing plant receiving area" because it would be cost prohibitive to retrofit existing fish processing plant designs to meet the meat and poultry plant models.

Response: Consistent with the meat regulations in 9 CFR 307.2, 9 CFR 533.4 requires the official Siluriformes establishment to provide docks and receiving rooms, designated by the operator of the official establishment, in consultation with the FSIS frontline supervisor, for the receipt and inspection of Siluriformes, Siluriformes products, and other products. These spaces are necessary

to facilitate unloading and staging of products and to minimize the potential for cross-contamination that may occur through these activities. FSIS does not believe there is a meaningful distinction between "docks and receiving rooms" and "plant receiving area" and is not modifying the regulatory language in this final rule. The Agency does not anticipate that catfish plant designs will need to be significantly modified to comply with the regulations that contain this language.

Comment: A trade association and a domestic processor asserted that the consistent work schedules and two weeks advance notice for schedule changes requirements, as proposed, will pose undue hardship on the catfish industry. The comments explained that operational hours necessarily fluctuate according to seasonal peaks, availability of fish, size of fish harvested, and other factors.

Response: As proposed, the final regulations for a fish establishment's schedule of operations (9 CFR 533.5) cross-reference the meat regulations (9 CFR 307.4) that define a shift and the basic workweek and require each official establishment to submit a work schedule to their District Manager for approval. In addition, each official

establishment will be required to maintain a consistent work schedule. Deviations from the work schedule must be submitted to the District Manager at least two weeks in advance. Establishments may also request overtime inspection, if needed; however, seasonal demands can only be met as resources allow. Consistent work schedules and prior notification for schedule changes are necessary to ensure that the Agency can maintain an inspector presence during establishment operations. However, the Agency does not want to pose undue hardships on establishments, and District Managers will take into consideration any work schedule change request.

H. Definitions

1. "Adulterated"

Comment: A domestic processor specifically requested that FSIS delete the phrase "...an animal which has died otherwise than by slaughter," paragraph (5) under the proposed "adulterated" definition (9 CFR 531.1). In addition, a trade association suggested FSIS use the definition of "adulterated" to mean any food safety hazard as defined in 21 CFR part 123.

Response: As discussed in the proposed rule (76 FR 10441), the FMIA defines as adulterated a food product

that is, in whole or in part, the product of an animal that has died otherwise than by slaughter (21 U.S.C.601(m)(5)), and the proposed "adulterated" definition in 9 CFR 531.1 is the same as the definition in the meat regulations (9 CFR 301.2). FSIS continues to view fish that died under circumstances other than the controlled circumstances of commercial fish harvesting and processing as adulterated under this provision of the FMIA and unacceptable for food. In cases where dead, dying, diseased, or otherwise unfit fish are in commerce, it may be necessary for the Agency to apply the detention, seizure, and condemnation provisions of the Act (21 U.S.C. 672, 673).

2. "Slaughter" and "Slaughterhouse"

Comments: Several comments suggested various definitions of the term "slaughter." A consumer advocacy group urged FSIS to provide a clear definition of slaughter that listed various acceptable methods of slaughter. A domestic processor suggested that "slaughter" be defined as "when the head is removed for processing." A trade association stated that the catfish industry recognizes that slaughter, under controlled

conditions, occurs at the de-header machine within the processing facility.

An organization of regulatory officials recommended that FSIS define "slaughterhouse" to include locations where catfish may have died under conditions other than the controlled circumstances of commercial processing. This comment further added that a definition for "slaughterhouse" should also include locations where "wild-caught" catfish are processed.

Response: After considering the comments, FSIS has concluded that the definition of "slaughter" as intentional killing under controlled conditions (9 CFR 531.1) is applicable to various slaughter methods, and it is not necessary to list all of the various methods in the regulations. In addition, the Agency does not see value in defining the term "slaughterhouse," as the definition includes the phrase "under controlled conditions." FSIS would consider fish that died under circumstances other than the controlled circumstances of commercial fish harvesting and processing to be adulterated under the FMIA and unacceptable for food, e.g., a fish that fell onto the pavement in the delivery area of a processing plant and

lay there until it died would not be acceptable for human food.

3. "Farm-raised" and "Wild-Caught"

Comment: A trade association suggested that the proposed definition for "farm-raised" (9 CFR 531.1) be amended to require the control of enclosed bodies of water to prevent contamination. A domestic processor asked that the proposed definition be amended to include "raised in an enclosed environment of a clean, private, controlled water source."

A comment from a foreign government described the proposed definition for "farm-raised" as unreasonable because it does not consider the diversity of raising methods (e.g., breeding in pools and floating cages) and is inconsistent with "the actual growth situation of catfish" in their country. The foreign country stated that the floating cage method is the general method used in their country, as well as other foreign countries.

A member of academia stated that "wild-caught" catfish should be subjected to the same provisions of the rule as "farm-raised" catfish, including the testing requirements of the fish and water. A consumer advocacy group urged FSIS to require catfish establishments to

segregate "wild-caught" fish from "farm-raised" fish during slaughter and processing. In addition, an aquaculture scientist stated that freshwater aquaculture needs an inspection and food safety system that differs from marine "wild-caught" seafood because hazards, their sources, and interventions differ significantly.

Response: Proposed 9 CFR part 534 outlines the pre-harvest standards that FSIS will require to ensure that the environmental conditions and source waters in which the fish are grown will not render the fish unfit for food. These regulations require that fish harvested for human food, whether wild-caught or farm-raised, must not have lived under conditions that would render them unsound, unwholesome, unhealthful, or otherwise unfit for human food (9 CFR 534.1) so the fish would not be "adulterated" as the term is defined in 21 U.S.C. 601(m)(3) in the FMIA. The definition of "farm-raised" in 9 CFR 531.1 of the regulations is intended to cover a variety of fish-raising methods, including methods that involve raising the fish in pools and floating cages.

Although the domestic fish growing process primarily utilizes fish-raising ponds, FSIS recognizes that wild-caught fish may be commercially processed. 9 CFR 534.2

states that farmers of fish should monitor the water in which the fish are raised for the presence of suspended solids, organic matter, nutrients, heavy metals, pesticides, fertilizers, and chemicals that may contaminate fish. FSIS will inspect wild-caught and farm-raised fish processed in official establishments and test them for metals, dyes, pesticides, and animal drug residues. The Agency does not see the need for requiring the segregation of "farm-raised" and "wild-caught" fish as they are processed in an official establishment.

Comment: A consumer advocacy group requested that the manner by which the animal was raised, "farm-raised" or "wild-caught," be required on the label. A similar comment requested that "wild-caught" fish be labeled as such to distinguish them from "farm-raised" fish.

Response: FSIS is authorized under the FMIA to regulate the marking, labeling, and packaging of all Siluriformes products in commerce (21 U.S.C. 607). However, there is no statutory obligation to label fish with the raising claims "farm-raised," or "wild-caught." Establishments may choose to voluntarily label their finished product with such raising claims, if the claims are not false or misleading. Such claims for fish would

not require FSIS approval as required by 9 CFR 412.1(c) (3) and 541.7(g) .

As discussed below, the final rule (9 CFR 541.7(b)) requires that country of origin statements on the label of any covered commodity (fish, including fillets, steaks, nuggets, and any other flesh) sold by a retailer must comply with the AMS regulations (7 CFR 60.200 and 60.300). For these products, the AMS regulations require method of production information (wild or farm-raised).

I. Labeling

1. Mark of Inspection

Comment: Several domestic processors, a consumer advocacy group, and an organization of regulatory officials recommended that the Federal mark of inspection be similar to the current brand for meat, poultry, and egg products. Another comment requested that the official inspection legend for catfish be unique in design and applied only to all finished packaging and in-process transfer containers. One comment favored assigning a number to each catfish establishment. Several comments noted that it may be impractical to stamp all carcasses of whole, gutted fish due to the size of the product and suggested alternative measures be considered, such as

branding shipping containers, affixing inspection tags to lots, or marking invoices that accompany any shipments.

Response: Because all fish of the order Siluriformes are amenable species under the FMIA, FSIS will require the same inspection legend for those products as it does meat products (9 CFR 312.2, reproduced in 9 CFR 541.2, respectively). This inspection legend includes the number of the establishment. FSIS recognizes that it may be impractical to physically apply the inspection legend to whole, gutted, fish carcasses. Therefore, whole, gutted fish carcasses that have been inspected and passed at an official establishment, and that are intended for sale as whole, gutted fish may be stamped with the official inspection legend or properly packaged in an immediate container and then labeled with the official inspection legend, as well as with all other required labeling features (9 CFR 317.2). For all other Siluriformes fish products, the inspection legend will be required on the immediate container.

2. Species Identification and Prevention of False or Misleading Labeling Practices

Comment: One comment stated that FSIS should choose a rapid, accurate, and inexpensive method for catfish

species identification. Another comment stated that FSIS should choose a method that provides accuracy at the species level. One comment stated that catfish products should be identified according to the species of fish throughout processing regardless of the final packing step location.

Response: FSIS will determine fish speciation by appropriately validated methods which are published in the Chemistry Laboratory Guidebook on the FSIS Website at http://www.fsis.usda.gov/Science/Chemistry_Lab_Guidebook/index.asp . The methods chosen by FSIS are state-of-the-art and appropriate for their purpose in determining fish species identification.

The fish labeling regulations (9 CFR 541.7, cross-referencing part 317, subpart A) require the name of the product on the label (9 CFR 317.2(c)(1)). Product leaving an official Federal establishment for distribution in commerce for further processing would have to be properly identified with all applicable mandatory labeling features, including a product name. It would typically bear a statement of limited use, e.g., "for further processing" to limit distribution to another official Federal establishment. Because the product is intended

for further processing, and not for retail sale, some labeling features would not be required because they would meet an existing exemption, e.g., nutrition labeling (317.400 (a)(3)), safe handling instructions (9 CFR 317.2(1)(4), and net weight (317.2(h)(1).

Under the FD&C Act (21 U.S.C. 321d (a)), the term "catfish" is considered to be a common or usual name (or part thereof) only for fish classified within the family Ictaluridae; and labeling or advertising only for fish classified within that family may include the term "catfish." Species of Ictaluridae include, among others, Ictalurus punctatus, I. furcatus, and Pylodictis olivaris, which may be identified as "channel catfish," "blue catfish," and "flat-head catfish," on the labeling, if it is not false or misleading (9 CFR 541.7, cross-referencing part 317, subpart A, 9 CFR 317.8). Through fish speciation sampling and testing, FSIS will routinely verify that product is accurately labeled and not misbranded at official establishments and at import reinspection facilities.

3. Standards of Identity

Comment: A domestic processor requested that all catfish products (as examples, formed nuggets, patties,

cakes, gumbo) should contain at least 51 percent or more catfish.

Response: Product standards are intended to ensure that products sold under particular names have the characteristics expected by consumers. FSIS will, if necessary and appropriate, apply any of the existing meat regulatory standards in 9 CFR Part 319- that may be applicable, e.g., "meat stew" (9 CFR 319.304) to fish products. A mixture of Ictaluridae and other Siluriformes could be labeled with an accurate and truthful descriptive name identifying the Ictaluridae (catfish) and other species of the Siluriformes, e.g., "Catfish and Basa."

As stated in the preamble of the proposed rule, there are few further-processed fish products produced domestically (76 FR 10446), and FSIS is not aware of any fish standard-of-identity issues that require rulemaking. However, as provided in 9 CFR part 392, any person can petition the Agency to issue a regulation for a standard of identity.

4. Percent Approved Substances

Comment: A trade association asked that the percentage of sodium tripolyphosphate, where allowed in catfish products (generally 0.5 percent by weight of the

finished product), be explicitly addressed in the regulations to ensure that there is a uniform standard for domestic and foreign products.

Response: 9 CFR 544 states that no fish product may bear or contain any food ingredient that would render it adulterated or misbranded or that is not approved in 9 CFR part 424 of subchapter E. 9 CFR 424.21 lists food ingredients that are approved for use in the preparation of meat products if they are used for the purposes indicated, within the limit of the amounts stated, and under other conditions specified. FSIS will apply the purpose and amount of any food ingredients to fish products, if appropriate, and in consultation with FDA. The purpose and amount of sodium tripolyphosphate listed in the table for meat food products that would be applicable to fish products is 0.5 percent in the meat food product to decrease the amount of cooked out juices.

5. Net Weight and Retained Water

Comment: An aquaculture industry advocacy group stated that the net weight of Individually Quick Frozen (IQF) fish is not determined on a "thawed" basis, as suggested in proposed 9 CFR 541.7(b)(1). The commenter stated that while it is correct that the deglazed net

weight must be 100 percent of the stated net weight, the procedure to determine this weight, as found in the NIST Handbook 133, does not thaw the product but only requires the removal of the outer layer of ice, and that the product is maintained in a frozen state. Additionally, the commenter stated that the net weight for IQF seafood is determined on a frozen basis.

A domestic seafood distributor requested additional clarification on the section related to product moisture content and labeling because the proposed language is unclear on how to measure and label products that have undergone any kind of further processing. A foreign country's chamber of commerce stated that it would be impractical and serve no legitimate end to require catfish processors to calculate how much retained water is included in the production process.

Response: NIST Handbook 133 net weight test procedures for the ice-glazed catfish products state that the products are "deglazed" by placing the product under a gentle spray of cold water, and that the product should remain rigid (Section 2.6.2.2). FSIS will follow this procedure for determining net-weight compliance for ice-glazed fish. However, the NIST Handbook 133 test

procedure for Encased-in-Ice Product Only (Section 2.6.1.2), which includes frozen catfish, including IQF catfish, is to thaw the product before weighing.

As explained in the proposed rule, the Agency proposed requirements for the control of retained water in catfish (76 FR 10445). FSIS will not permit retained water-- water remaining in raw product after it undergoes immersion chilling or a similar process-- in the packaged product unless the official establishment is able to show, with data collected under a written protocol, that the retained water is an unavoidable consequence of the process used to meet applicable food safety requirements (9 CFR 441.10(a)). To determine the amount of water retained in the product retained from a chilling process, an establishment may use physical water pick-up tests, weighing the product before the chilling process, and again just prior to final packaging and labeling. This is necessary because the amount of water retained in the product in excess of naturally occurring moisture must be prominently declared on the label.

6. Safe Handling Instructions

Comment: A comment suggested that, to avoid confusion, one of the statements required within the safe

handling instructions (9 CFR 541.7, cross-referencing part 317, subpart A), "This product was prepared from inspected and passed meat and/or poultry," be modified to include the word "catfish" along with "meat and/or poultry."

Response: FSIS agrees that a safe handling statement referencing "meat and/or poultry" may potentially confuse consumers. Therefore, in this final rule, FSIS has modified the proposed codified language (9 CFR 541.7(a)) to require that the safe handling instructions rationale statement read, "This product was prepared from inspected and passed fish," and the labeling statements read, "Keep raw fish from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw fish."

7. Country of Origin Labeling

Comment: Several private citizens, trade groups, and domestic processors requested that FSIS require that the country in which the catfish was hatched and raised, as well as processed, appear on the finished product label.

Response: All shipping containers and immediate containers, as defined in 9 CFR 301.2, containing meat, including fish, imported into the United States for human

consumption, must bear the name of the country of origin (9 CFR 327.14, 327.15; 9 CFR 557.14, 557.15).

The proposed labeling regulations (9 CFR 541.7, cross-referencing 9 CFR, part 317, subpart A) require that catfish and catfish products be labeled in accordance with the Agricultural Marketing Service (AMS) country of origin notification labeling regulations in 7 CFR, part 65, subpart A (9 CFR 317.8(b)(40)). The AMS regulations require that covered commodities (as defined in 7 CFR 60.105) sold by a retailer, whether individually, in a bulk bin, display case, carton, crate, barrel, cluster, or consumer package contain country of origin and method of production information (wild or farm-raised) (7 CFR 60.200 and 60.300). The proposed rule cross-referenced AMS' Country of Origin Labeling (COOL) requirements for meat commodities. In this final rule, the Agency is correcting the regulatory text, by adding a paragraph to 9 CFR 541.7, to cite 7 CFR part 60, subpart A, "Country of Origin Labeling for Fish and Shellfish." Establishments are not required to label their fish products with country of origin labeling. However, if an establishment chooses to place a label on a Siluriformes fish or fish product covered commodity with a country of origin statement, it

must comply with the AMS regulations. Labels with country of origin claims can be generically approved, i.e., the labels can be prior-approved by the Agency without submitting such labels to FSIS for sketch approval (9 CFR 412.2). Generic label approval requires that all mandatory label features be in conformance with FSIS regulations.

J. Pre-Harvest and Transport Conditions

Comment: FSIS received several comments requesting that the final rule include performance standards for pre-harvest environmental and water conditions and transportation. A trade association stated that an FSIS monitoring program for water quality is unnecessary, and that water quality should be tested on a periodic basis, perhaps annually. Another trade association requested that any performance standards that the Agency develops should be clearly spelled out with adequate explanation for regulated parties to fully understand the new requirements.

Response: The general pre-harvest requirements in 9 CFR part 534, require that fish harvested for use as human food must have grown and have lived under conditions that will not render them unsound, unwholesome, unhealthful, or

otherwise unfit for human food. 9 CFR 534.2 requires that farmers of catfish monitor the water in which the fish are raised for suspended solids, organic matter, nutrients, heavy metals, antimicrobials, pesticides, fertilizers, and industrial chemicals that may contaminate the fish. FSIS will collect samples of feed, fish, and pond water on a case-by-case basis, for cause, i.e, if FSIS finds residues or diseases in tissue at slaughter. Establishments will be required address the hazards associated with "wild-caught" fish as part of their HACCP plans (9 CFR 417.2), and FSIS will verify that they carry out this monitoring.

In addition, 9 CFR 534.4 requires that vats or other containers transporting fish must be maintained in a sanitary condition, and that sufficient water and sufficient oxygen must be provided to the vats that hold the fish to ensure that the fish are delivered to the processing establishment not adulterated.

Comment: Several commenters stated that the regulations must address the quality of water used in transport vehicles. One trade association stated that proposed 9 CFR 534.4 should be amended to include the phrase, "... sufficient unpolluted and uncontaminated water

and sufficient oxygen or aeration must be provided to the vats....”

Response: FSIS agrees with the comments but finds that no changes are necessary in response to the comments. In point of fact, the proposed regulations provided for the transport conditions the comments seek. Thus, the final regulation requires that sufficient water and oxygen be provided, and that vats or other containers be maintained in a sanitary condition, which includes the water in the vats (9 CFR 534.4). In addition, the regulations require that fish harvested for use as human food have been grown and have lived under conditions that will not render them or the products made from them unsound, unwholesome, unhealthful, or otherwise unfit for human food (9 CFR 534.1).

Comment: A trade association and several domestic processors stated that it is not uncommon for live fish to come in contact with dead, dying, or diseased catfish during transport.

Response: FSIS recognizes that live fish may, on occasion, come in contact with dead, dying, or diseased fish during transport. However, incidental contact during transport with dead, dying, or diseased fish would not

automatically render an otherwise healthy fish adulterated. Under 9 CFR 548.2, adopted as proposed in this final rule, the establishment is required to prevent unsound, unhealthful, unwholesome, or otherwise unfit ingredients from being used in the preparation of products. 9 CFR 534.4 states that any fish that are dead, dying, diseased, or contaminated with substances that may adulterate catfish products are subject to condemnation at the official fish processing establishment. In cases where dead, dying, diseased, or otherwise unfit fish have entered commerce, it may be necessary for the Agency to apply the detention, seizure, and condemnation provisions of the Act (21 U.S.C. 672, 673).

K. Pathogen Reduction and Tolerances for Animal Drugs

Comment: FSIS received several comments requesting that the final rule include performance standards for pathogen reduction.

Response: In the preamble of the proposed rule (76 FR 10444), FSIS stated that it planned to implement a pathogen reduction program for catfish that would be similar to that for other classes of raw product subject to the FMIA. After completing a study to determine the national baseline prevalence and levels of Salmonella on

raw catfish, FSIS will conduct regular testing in processing establishments for the purpose of measuring industry performance against the baseline. If, after observing the industry's performance, the Agency determines the need for performance standards, it will publish the planned standards in the Federal Register, for public comment.

Comment: Several comments suggested that the Agency stipulate "zero tolerance" for malachite green, crystal violet, enrofloxacin, ciprofloxacin, and other antimicrobials prohibited for use in the U.S. One comment requested that FSIS add regulatory requirements for appropriate disposition of catfish and lots of catfish found positive for these substances. Another comment asked that FSIS specify that only antibiotics approved for use in U.S farm-raised catfish be permitted for use in all catfish products sold in the United States, foreign or domestic.

Response: The Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) have statutory authority for establishing antibiotic and other animal drug tolerances for meat, including fish. FSIS works with the EPA and the FDA to control drug, pesticide, and

contaminant residues including antibiotics in meat products, including fish, by testing animal tissues to verify that tolerance levels are not violated. Fish or fish products and lots of fish containing violative residues of the drugs or other chemicals including those the commenters listed would be considered adulterated and subject to condemnation (9 CFR 539.2).

L. Limits for Retail Quantities

Comment: A domestic processor stated that a retail purchase is generally less than 30 pounds, and non-household consumers would purchase 60 pounds or more. An organization of regulatory officials remarked that the retail purchase limits stated in the proposal seemed reasonable, although difficult to verify.

Response: FSIS is providing an exemption for retail stores and restaurants (9 CFR 532.3, paralleling 9 CFR 303.1(d) and (e)), using the poultry exemption regulations set out in 9 CFR 381.10 as a model. The final regulations provide a limit of 75 lbs. (single-sale) for an individual household purchase of fish to be considered a retail purchase; the corresponding limit for a non-household consumer would be 150 lb. Historically, these limits have

been accepted as realistic, and, therefore, FSIS is not changing the limits in this final rule.

M. Hard Copy Information

Comment: A domestic food processor requested that FSIS simplify and minimize the collection and transfer of hard copy information.

Response: FSIS is taking steps to minimize the use of hard copy. Inspection assignments in the fish inspection program will be incorporated into FSIS's computerized PHIS, as appropriate. Establishments have access to PHIS. The Application for Federal Inspection (FSIS Form 5200-2) and the Application for Label Approval and Instructions (FSIS Form 7234.1) are available in fillable Portable Document Format (PDF) on the FSIS Website. The electronic Label Submission and Approval System (LSAS) is also available to fish establishments that do not or cannot have their labels generically approved.

FSIS will provide for the electronic submission of information that it collects from entities that will come under its fish inspection regulations, where applicable. The Agency will continue to work to enhance its capacity for the electronic collection of information.

N. Other Comments

1. Exemptions and Periodic Auditing

Comment: A small domestic catfish processor requested that establishments that process less than 10,000 lb. of catfish products per week be exempted from the day-to-day FSIS mandatory inspection requirements. Additionally, the comment deemed a periodic audit system more appropriate for small scale operations than a mandatory inspection system. A similar comment suggested that the size of the catfish farm be taken into consideration when determining which farms are to be inspected.

Response: The FMIA does not provide an exemption for fish processors that produce less than a specified amount of product. In addition, the exemptions for custom and farm slaughter and processing or other exemptions do not apply to fish (21 U.S.C. 623). The FMIA provides for the examination and inspection of conditions under which fish are raised. This requirement applies to all farms that supply fish to Federal establishments, regardless of the size of the farm.

However, as discussed in Section XII, "FSIS Implementation," through its 18-month transitional period,

the Agency is providing establishments ample time to prepare and comply with the final regulations. In addition, during the 18-month transitional period, the Agency will exercise broad enforcement discretion, focusing particularly on preventing adulterated or misbranded Siluriformes fish and fish products from entering commerce. After the 18-month transitional period, FSIS will fully enforce all of the final regulations.

2. Use of Program Seals

Comment: Some domestic processors and a trade association claimed that requiring a program employee to affix a seal to any means of conveyance will cause processors undue hardship, especially if program employees are unavailable during shipping times. Commenters contend that it is unnecessary and impractical to require the sealing of trucks, since the boxes of product inside the truck are inspected and sealed and are delivered to multiple locations.

Response: A means of conveyance (e.g., a truck) transporting inspected and passed fish products and bearing the official inspection legend (9 CFR 541.2; 9 CFR 325.5) is not required to be sealed by FSIS. The

requirement for sealing railroad cars, motortrucks, or other means of conveyance applies when inspected and passed fish products are being transported from one official establishment to another, and the products are "unmarked", i.e., they do not contain the official mark of inspection. Shipping inspected and passed, and properly marked, product does not require FSIS inspection and typically occurs outside the hours of inspection. FSIS did not change these provisions because establishments have flexibility in timing the application of seals to shipments.

O. Cooperation with States

Comment: An organization of regulatory officials requested that FSIS develop cooperative agreements with States for the inspection of catfish and catfish products.

Response: Under 9 CFR 560.1, FSIS may cooperate with any State in developing and administering a fish inspection program that has requirements that are "at least equal to" the requirements of the FSIS inspection program. When resources allow, FSIS will enter into new State-Federal Cooperative Agreements under which the Agency will cooperate with, and provide assistance to, States carrying out inspection programs for fish and fish

products that are to be sold intra-State. In addition, selected fish establishments in States that have and continue to maintain an "at least equal to" State meat inspection program will be eligible to ship their fish products across State lines and export them to foreign countries. In this final rule, FSIS is amending 9 CFR part 560 to include a paragraph specifically referencing 9 CFR 321.3, for the Cooperation of States for the Interstate Shipment of Carcasses, Parts of Carcasses, Meat, and Meat Food Products.

P. Outreach and Training

Comment: A trade association representing the storage industry asked that FSIS initiate substantial industry outreach to ensure regulated parties fully understand any new requirements and the phased-in implementation.

Response: FSIS intends to develop necessary outreach materials and hold sessions to inform and educate fish establishment owners and operators of the regulatory requirements contained in the final rule. The timing of the 18-month transitional period is based in part on the need to ensure that domestic as well as foreign regulated parties understand FSIS's requirements. The

implementation strategy is discussed in Section XII, and implementation information will also be posted on the FSIS Website.

XII. FSIS Implementation

FSIS proposed a four-phase approach to implementing the catfish inspection rule, but did not provide timeframes for implementation (76 FR 10452). The final rule provides an effective date, 90 days after its publication, and an 18-month transitional period until the regulations are fully enforced.

FSIS has given careful consideration in determining the nature of the inspection coverage that it will provide during the 18-month transitional period and once the rule is fully effective. In the proposed rule, FSIS used the term "continuous inspection," but did not define what this would mean. The Egg Products Inspection Act uses the term "continuous inspection" (21 U.S.C. 1034(a)), and FSIS has interpreted it to mean that the Agency must have an inspector at an egg products plant whenever the plant is processing eggs. FSIS does not believe that Congress intended FSIS to provide this level of inspection coverage in establishments that slaughter and slaughter and process fish. Congress provided for inspection of fish in Section

606 of the FMIA (21 U.S.C. 606(b)). FSIS's longstanding and well-known interpretation of Section 606 is that it only requires inspection once per shift. If Congress had intended something different, it is reasonable to presume that it would have put the provision for inspection of fish in a different section. Second, the 2014 Farm Bill Joint Explanatory Statement of the Committee Conference¹⁰ states: "There exists scientific evidence that demonstrates that the use of substances such as malachite green, nitrofurans, fluoroquinolones, and gentian violet during the stages of production can result in continued presence in edible Siluriformes products. The managers believe that continuous inspection of farm-raised species is a legitimate tool to address concerns." In this statement, it is pretty clear that Congress was using "continuous" in its ordinary meaning of uninterrupted. Congress was saying that the FSIS model of performing inspection on an ongoing basis of once per shift is more consistent with the type of inspection necessary than the FDA model of sporadic inspection (once per year or more). Thus, FSIS believes that it will be providing the coverage

¹⁰ <http://docs.house.gov/billsthisweek/20140127/CRPT-113hrpt-HR2642-SOM.pdf>

that Congress intended and that it is not necessary to use "continuous" in the regulations.

Following its interpretation of the language in the Farm Bills, the 2014 Farm Bill Joint Explanatory Statement of the Committee of Conference and the FMIA, FSIS will, at the start of implementation, assign inspection program personnel to be present during all hours of operation on a daily basis at domestic establishments that slaughter and slaughter and process Siluriformes fish and fish products. At the start of implementation, FSIS will assign inspection program personnel to conduct inspection at processing-only facilities at least quarterly.

At the end of the 18-month transitional period, inspection program personnel will continue to be assigned to conduct inspection during all hours of operation at slaughter and slaughter and processing establishments for some period of time. Based on FSIS's findings during and after the transitional period, it may adjust inspection frequency in slaughter and slaughter and processing establishments in the future. FSIS will establish criteria it will follow in determining how inspection will be adjusted at these establishments and will make these criteria available to the public. At the end of the 18-

month transitional period, inspection program personnel will be assigned at least once per day per shift at processing only establishments.

During initial implementation, FSIS will provide domestic Siluriformes fish and fish products establishments with guidance to ensure that they understand the new requirements. During the 18-month transitional period, if FSIS finds that an establishment has produced adulterated product (e.g., product that contains a violative residue or other adulterant or has been produced under insanitary conditions that result in direct product contamination) or has misbranded product by labeling it "Catfish" when the product does not contain fish of the family Ictaluridae or intentionally over-declaring the net weight, FSIS will prevent the product from going into commerce or will take action to ensure that it is removed from commerce. If FSIS finds any other noncompliance with these regulations, FSIS will document its finding and work with the establishment to address the problem in a timely manner.

FSIS will conduct sampling and testing of Siluriformes fish and fish products for species and residues to ensure that product is not adulterated or

misbranded. FSIS has developed a testing program that currently includes the capacity to test for malachite green, nitrofurans, veterinary drug residues (including some floroquinolones), gentian violet, metals, and pesticides (See Table 2, below). Also during the first 18 months, as noted in the Comment and Responses (Section XI), FSIS plans to commence collection of Salmonella data to determine the national baseline prevalence and levels of Salmonella on raw Siluriformes fish.

Table 2. Projected FSIS Fish Sampling Plan

# Samples per year	Type of Sample	Tests at Eastern Laboratory	Tests at Western Laboratory
100 (at each laboratory)	Domestic	<i>Salmonella</i> , Speciation, Metals, Dyes, and Veterinary Drug Residues (MRM)	<i>Salmonella</i> , Pesticides, Veterinary Drug Residues (MRM), and Nitrofurans
50 (at each laboratory)	Import	<i>Salmonella</i> , Speciation, Metals, Dyes, and Veterinary Drug Residues (MRM)	Pesticides and Nitrofurans

By the effective date of this final rule, [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER], foreign countries with establishments that are exporting Siluriformes fish and fish products to the United States, and that wish to continue to do so, are required to submit written

documentation identifying a list of establishments (with the establishment name and number) that currently export and will continue to export Siluriformes fish and Siluriformes fish products. Foreign countries must also provide written documentation to demonstrate that they currently have laws or other legal measures in place that provide authority to regulate the growing and processing of fish for human food, and to assure compliance with FDA's good manufacturing practices, Hazard analysis and Hazard Analysis and Critical Control Point (HACCP) plans, sanitation control procedures, and other regulatory requirements in 21 CFR part 123, Fish and Fishery Products. This initial documentation will not be evaluated to determine the equivalency of the foreign country's inspection system to that of the United States, but to establish that the Siluriformes fish and fish products exported to the United States are produced under a foreign country's authority and meet FDA's regulatory requirements. A foreign country may provide FSIS with any of the following written documentation:

- pursuant to 21 CFR 123.12(a)(2)(ii)(B), copies of foreign inspection continuing or lot-by-lot certificates that the imported fish products are or

were processed in accordance with requirements in 21 CFR part 123; or

- pursuant to 21 CFR 123.12(a)(1), an active memorandum of understanding (MOU) or similar agreement between the foreign country and FDA that covers Siluriformes fish or fish products and documents the equivalence or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the current situation between the signing parties, and is functioning and enforceable in its entirety; or
- an active memorandum of understanding (MOU) or similar agreement between the foreign country and FDA that covers the food safety of its products; or
- a checklist of the country's regulatory control system, procedures, to demonstrate the competent authority's control and ability to enforce a HACCP-based control program; or
- a side-by-side comparison of the country's or each processor's HACCP program with 21 CFR part 123; or

- a side-by-side comparison of the country's or each processor's sanitation program with FDA's GMP for sanitation at 21 CFR part 110; or
- for canned fish, a comparison of the country's or each processor's low-acid canned food and acidified food program with FDA's (at 21 CFR parts 108, 113, and 114); or
- a third-party certification of the country's or each processor's compliance with FDA requirements; or
- data and information that foreign countries submitted in response to any FDA Import Alert.

The initial documentation can be submitted to:

Food Safety and Inspection Service
OPPD/International Equivalence Staff
1400 Independence Avenue, SW
Room 2145, South Building
Washington, DC 20250-3700

After a foreign country submits its documentation, FSIS will evaluate its acceptability and notify the

foreign country if any clarifications or additional documentation are necessary. For additional information and guidance on the initial documentation requirements, foreign countries are encouraged to contact FSIS's, Office of Policy and Program Development's International Equivalence Staff at the address above, by phone (202) 720-0082, by Fax: (202) 720-7990, or Email: InternationalEquivalence@fsis.usda.gov.

Starting on the effective date of the rule, [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER], or within a reasonable amount of time thereafter, FSIS will maintain a list on its Website of foreign countries that have provided the list of establishments and met the initial documentation requirement. During the 18-month transitional period, Siluriformes fish and fish products exported to the United States from foreign counties that have not met the initial documentation requirement will be refused entry. If, during the transitional period, a foreign country wants to add establishments to its list, it must notify FSIS using the contact information above. The foreign country should explain the circumstances

behind adding the establishment and provide assurances that the facility conducts sanitary operations and produces wholesome product. FSIS will make determinations on adding establishments on a case-by-case basis, taking into account the information submitted.

FSIS will recognize the initial documentation foreign countries submit, until full enforcement of the rule, at the end of the 18-month transitional period, September 1, 2017, or FSIS determines whether the foreign inspection systems are equivalent to that of the United States, whichever occurs first. Foreign countries seeking to continue exporting Siluriformes fish and fish products to the United States after the 18-month transitional period, September 1, 2017, are advised to start submitting their documentation showing that they have an equivalent inspection system as soon as possible during the transitional period. The FSIS equivalency process is described fully on the FSIS Website at:

<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/equivalence>. In any event, foreign countries must submit this information no later than the date of full enforcement, at the end of the 18 month transitional period, September 1, 2017. If foreign

countries have done so, they may continue to export until such time that FSIS makes a determination with respect to the equivalency documentation submitted by the foreign country, and FSIS's determination is negative (i.e., FSIS determines that the foreign inspection systems are not equivalent to that of the United States). If FSIS determination is positive, trade can continue.

On the effective date, [INSERT DATE 90 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER], at each official import inspection establishment, imported Siluriformes fish and fish product shipments will be reinspected and subjected to species and residue testing on at least a quarterly basis. At the end of the 18-month transitional period, on the date of full enforcement (September 1, 2017), all imported Siluriformes fish and fish product shipments will be reinspected, just as all imported meat and poultry products from equivalent countries that export product to the United states are reinspected.

By the end of the 18-month transitional period, foreign countries must apply, under FSIS' regulations, for equivalency determinations. If a country does not initiate a request for equivalency and provide documentation showing its system is equivalent by the end

of the 18-month transitional period, i.e., the date of full enforcement, September 1, 2017, FSIS will refuse entry to Siluriformes fish and fish products exported from that country. When a foreign country initiates a request for equivalency and provides documentation during the 18-month transitional period, if additional information is required, FSIS will request that the foreign country respond or resubmit complete equivalence documentation within 90 day of receiving FSIS's request. If, after the 18-month transitional period, the foreign country has failed to respond to FSIS's request within 90 days of receiving the request, FSIS will refuse entry to Siluriformes fish and fish products exported from that country. Based on its review of the information and documentation that the country submits, FSIS will tentatively decide whether the foreign country's inspection system and requirements are equivalent to FSIS', and if so, will plan an on-site audit of the country's Siluriformes fish and fish products inspection system. If FSIS also tentatively finds the foreign country's inspection system equivalent based on the audit, FSIS will publish a proposed rule in the Federal Register announcing the results of the document review and on-site

audit, proposing to add the country to its list of eligible exporting countries (9 CFR 557.2(b)). After analysis of public comments, FSIS will publish a final rule announcing its determination on the country's eligibility.

XIII. Executive Orders 12866 and 13563 and the Regulatory Flexibility Act

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated an "economically significant" regulatory action under section 3(f) of Executive Order (E.O.) 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget under E.O. 12866. The Regulatory Flexibility Act requires an assessment of the effects of the final rule on small entities. This assessment is in this Section XIII, part J., below.

FSIS is adopting, with changes, the preliminary regulatory impact analysis (PRIA) Scenario #1 alternative, published in the proposed rule, as the final regulatory impact analysis (FRIA) in this final rule. The changes to the PRIA are the result of the 2014 Agricultural Act amendments to the FMIA mandating that "all fish of the order Siluriformes are amenable species," public comments, and updates that include more current costs, prices, fish consumption data, fish demand data, fish supply data, fish exports, fish imports, and the changing structure of the Siluriformes fish industry. These include:

- Updated baseline information to reflect changes in the industry.
- Updated costs and prices for the more current markets.
- Updated assessment of the potential public health benefits of the final rule, in the break-even analysis, to reflect a lower average direct cost of \$2,423 (in 2010 dollars) for a clinical case of salmonellosis.¹¹

¹¹ The FSIS estimate for the average cost of salmonellosis illnesses (\$2,423 per case - 2010 dollars) was developed using the USDA, ERS Foodborne Illness Costs Calculator: Salmonella (June-2011). FSIS updated the ERS calculator to include Scallan case distribution for Salmonella. Scallan, E., Hoekstra, R., Angulo, F., et.al. (2011).

- Updated FSIS implementation schedule (see section XII, above).

A. Need for the Rule

FSIS inspection of Siluriformes is mandated by law and non-discretionary.

B. Baseline

Mandatory inspection of Siluriformes fish and Siluriformes fish products is a new program for FSIS. Currently, FDA does require a Seafood HACCP plan¹² for establishments that process seafood, including Siluriformes fish and Siluriformes fish products. A Seafood HACCP plan requires covered establishments to have completed a hazard analysis, be able to take corrective actions, conduct on-going verification activities, review records, conduct training, and establish and implement sanitation control procedures. In the preamble of the proposed rule and the PRIA, Table 2, FSIS provided an overview comparison of the FSIS, FDA and USDC/NMFS/NOAA inspection system requirements.

In establishments that request inspection services under the Agricultural Marketing Act of 1946,

Foodborne Illness Acquired in the United States - Major Pathogens. Emerging Infectious Diseases, 17 (1), pp.7-15.

¹² More additional information, see the FDA Seafood HACCP regulations and guidance at <http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006764.htm>

USDC/NOAA/NMFS routinely inspects domestic seafood, including Siluriformes fish and Siluriformes fish products, on a fee-for-service basis. On average, domestic Siluriformes fish establishments' contract with NMFS for that service annually for an annual cost of \$1,340.00 thousand. See the NMFS.gov Website for more information on that service. However, neither FDA nor USDC/NOAA/NMFS inspects Siluriformes fish production facilities (fish farms); or transporters of live Siluriformes fish. Also, the USDC/NOAA/NMFS does not inspect commercial feed mills that manufacture fish feed products or rations for Siluriformes fish farms.

C. Catfish Consumption and Prices

Data on Siluriformes supply and demand is limited. Recently, the U.S. Farm-Raised Catfish Industry 2013 Review and 2014 Outlook¹³ provided industry statistics for the Siluriformes Industry:

- U.S. farm-raised catfish consumption of the order Siluriformes was 0.5 pounds per person in the 2012 "Top 10" fish and seafood consumption list for Americans, who consumed 14.6 pounds of fish and

¹³ Hanson, T and D. Sites. "2013 U.S. Catfish Database". Fisheries and Allied Aquacultures Department Series No. 1. Alabama Agricultural Experiment Station. Auburn University. Auburn, Alabama. April 2014. Sources: USDA National Agricultural Statistics Service (NASS) and Mississippi Agricultural Statistics Service (MASS).

- seafood per year in total. In 2004, catfish consumption was 1.1 pounds when total seafood consumption for Americans was 16.6 pounds. The U.S. catfish industry has been on a contracting course since a high mark in 2003 when 662 million pounds of round weight (i.e., live weight) catfish were processed. In 2013, 334 million pounds were processed, up 33.4 million pounds (11 percent) from 300 million pounds processed in 2012; but a 50 percent decrease since the 2003 peak.
- In 2002 there were more than 2200 catfish operations with sales and distribution. By 2012, that number was down by nearly 50 percent to about 1200 operations (NASS). There were 624 domestic producers reported by NASS in January 2013 down from 718 in 2012 and down from more than 1800 in 1989. Low prices and prior years of reduced production and processing have led to hatchery operators reducing their number of fingerlings and broodstock in stock.
 - Imports of frozen Siluriformes fish fillets increased by 44 million pounds (18 percent) to 281 million pounds in 2013; and imports now account for 75

percent of all U.S. sales of frozen Siluriformes fish fillet product.

- There were 71,725 acres of water in U.S. catfish production in January 2014, down 14 percent from 2013. Current production acreage for the top three catfish producing states, Alabama, Arkansas and Mississippi, was down 10,925 acres (15 percent) to 64,075 acres. There were 196,760 acres of water in U.S. catfish production in January 2002 (NASS).
- The average price received by domestic producers was \$0.974 per pound in 2013, down \$0.002 per pound from the 2012 average price of \$0.976 per pound. In 2013 there was a \$0.294 per pound difference between high (November, \$1.113 per pound) and low (January, \$0.819 per pound) pond bank prices received during the year.
- Domestic in-pond inventories of foodsize fish in January 2014 were down 10 percent from January 2013 levels. Stocker inventory was down 14 percent from January 2013 levels. Fingerling weight (and number) inventory was up 4 percent (and down 21 percent) from January 2013 levels. Broodfish pounds were up 5 percent.

- Domestic catfish feed prices (32 percent protein) in 2013 averaged \$483/ton, up \$14/ton (3 percent) over the 2012 average feed price of \$469/ton. Of note, 2013 feed prices peaked in July (\$494/ton) while the lowest feed price in 2013 occurred in November (\$425/ton).
- The average wholesale price received by domestic catfish processors was \$3.04 per pound in 2013, down \$0.04 per pound from the 2012 average price of \$3.08 per pound. In 2013 there was a \$0.60 per pound difference between high (October, \$3.36 per pound) and low (January, \$2.76 per pound) prices received during the year.

For the affected United States domestic industry, FSIS projects that there are 624 operating Siluriformes fish farms and fish hatcheries; 18 establishments that slaughter and conduct primary processing of Siluriformes fish and Siluriformes fish products; and 200 establishments that are (1) further or secondary processors of only Siluriformes fish and Siluriformes fish products, (2) live-fish loaders/haulers/wholesalers of Siluriformes fish, (3)

wholesalers/brokers/importers/exporters of Siluriformes fish and Siluriformes fish products, and (4) Siluriformes fish feed mills. In 2012 the number of catfish operations with sales and distribution numbered 1200. In 2013, the number of catfish operations with sales and distribution numbered 842. See Table 5, below, for details.

The Agency based those projections on the USDA National Agricultural Statistics Service (NASS) (2013-2014 Catfish Production Report); Food and Drug Administration (FDA) (2014)¹⁴; the Dun and Bradstreet (DNB) business database (2014); import records of the U.S. Department of Homeland Security (DHS) Customs and Border Protection (CBP) (2009-2013);¹⁵ and the U.S. Census Bureau Economic Census (2012).

D. Alternative Regulatory Approaches Considered

Initially, FSIS considered two basic regulatory approaches to Siluriformes fish and Siluriformes fish products inspection: 1) a more command-and-control approach, or 2) the Pathogen Reduction/Hazard Analysis and Critical Control Points Systems (PR/HACCP) approach the Agency adopted in 1996 (61 FR 38806; July 25, 1996).

¹⁴ Email correspondence between the U.S. Food and Drug Administration and the Food Safety and Inspection Service. February 26, 2014.

¹⁵ U.S. Department of Homeland Security (DHS) Customs and Border Protection (CBP) import records of 2009 through 2013.

FSIS, however, rejected the command-and-control approach in 1996 with the adoption of the Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) Systems final rule (61 FR 38806; Jul.25, 1996). Moreover, command-and-control approaches are generally disfavored, while less burdensome, more flexible approaches are generally preferred, under Executive Order 12866 and OMB Circular A-4.

For the final rule, the Agency is adopting for Siluriformes fish and Siluriformes fish products, as it has for meat and poultry products, the PR/HACCP approach to inspection which focuses on the verification of an establishment's food safety system, which consists of an establishment's HACCP plan, Sanitation SOPs, and prerequisite programs.

Further, FSIS considered two regulatory alternatives for the PR/HACCP approach:

1. The first alternative considered is the same as the final rule except the Agency implements this alternative with additional assignments of inspection program personnel (IPP) at fish ponds, fish hatcheries, fish feed mills, processing-only establishments, and for live-fish capturing/loading/transporting to the slaughter

establishments. Under this alternative, FSIS would implement the regulation in a manner consistent with previous rulemaking proposals.¹⁶ The additional cost of this alternative to the Agency would be as outlined in the published PRIA (scenario 1) of the Proposed Rule, and would add approximately \$13 million annualized cost (7 percent interest over 10 years)) to the final rule. We would not expect additional potential benefits of increased FSIS inspection on reducing illnesses, beyond those additional potential benefits from the implementation of the final rule.

2. The second alternative considered is the same as the final rule except the Agency implements the final rule in three phases of 18 months for each phase, over a total of 4.5 years. Under this alternative, FSIS would implement the regulation in a manner consistent with previous rulemaking proposals.¹⁷ Presumably that would limit the prevention of salmonellosis cases in the first three years relative to the first alternative.

That delay in implementation would have additional direct costs to the domestic industry of paying for

¹⁶ "Mandatory Inspection of Ratites and Squabs." May 7, 2001 (66 FR 22899).

¹⁷ "Mandatory Inspection of Ratites and Squabs." May 7, 2001 (66 FR 22899).

contracted certification of fish and fish products for some of the affected facilities in order to meet stipulations in purchase contracts, such as with large grocery chains. The industry may be asked to initiate and maintain third-party inspection/auditing services (e.g., USDC/NOAA/NMFS) for a period of time until FSIS IPP are deployed, and, therefore, accruing additional costs (i.e., not accruing the projected cost-savings that would result from an earlier implementation of the final rule), such as for these third-party inspection/auditing services. The additional cost of this alternative to the industry and the Agency would be as outlined in the proposed rule (scenario 1), and would add approximately \$0.03 million annualized cost (7 percent interest over 10 years) to the final rule. It may also delay the potential benefits of increased FSIS inspection and detection on reducing illnesses. An extended transitional period may reduce the expected minimal costs to foreign entities. Foreign producers do not need to gather and submit information to FSIS. Rather, at the beginning of the transitional period foreign governments that wish to continue exporting Siluriformes products to the United States will have to submit documentation showing that they are compliant with

FDA requirements and a list of establishments that currently export Siluriformes products to this country. By the end of the transitional period, they will need to submit information to FSIS showing that they maintain an equivalent inspection system for such product. This transitional period will provide FSIS more time to work with these governments to provide guidance on what they need to submit. In addition, FSIS will have time to follow up with the country, if FSIS has questions or needs additional information. FSIS's efforts should lessen the possibility of trade disruptions, thereby minimizing the costs to foreign producers and any effects on the availability of product.

E. Expected Cost of the Final Rule

The final rule establishes all fish of the order Siluriformes as an amenable species. This is Scenario #1 in the proposed rule. The final rule, however, is to be implemented in 18 months, as outlined above in Section XII.

In the proposed rule, the Agency discussed that, since the domestic fish industry, including Siluriformes, must comply with the Food and Drug Administration's Seafood Hazard Analysis Critical Control Point (HACCP) and

other regulatory requirements, and that some of the domestic establishments that slaughter fish of the order Siluriformes contract with the USDC/NOAA/NMFS for voluntary, fee-for-service inspection and certification program, the Agency thinks, from observations during site visits, that many of the domestic Siluriformes fish and Siluriformes fish products industry would be compliant with many of the proposed requirements.

FSIS projects that all domestic Siluriformes fish and Siluriformes fish products establishments will be in compliance with the requirements for Sanitation SOPs and HACCP according to the implementation schedule of the final rule. From discussions with industry experts in the Cooperative Extension Services and USDC/NOAA/NMFS, FSIS believes that a significant share of the domestic Siluriformes fish and Siluriformes fish products industry is compliant with many of the individual final rule measures.¹⁸ Even though compliance rates for some HACCP-related activities may be relatively high, the performance of HACCP systems depends on how well all the elements -- hazard analysis, monitoring of critical control points and

¹⁸ For more information regarding the difference, see the Proposed Regulatory Impact Analysis, Table 2.

critical limits, recordkeeping, process control testing, and verification -- are being performed. In addition, the provisions of the final rule have additional costs to the domestic industry such as for meeting sanitation requirements (SSOP), new training, new labels¹⁹ for Siluriformes fish and Siluriformes fish products, new government office space and equipment, new equipment and operating costs for live fish transportation/hauling, and for new reinspection at import establishments.

The details of projected additional direct costs to the domestic industry, including the annual cost-savings of reduced payments of inspection fees to USDC/NMFS because of the implementation of the final rule are available at:

<http://www.fsis.usda.gov/wps/wcm/connect/63387be5-ca8e-442d-b047-f031f29a8a47/Siluriformes-RA.pdf?MOD=AJPERES>. A summary table of the costs is included in Table 3 (below). FSIS projects that the annualized cost to these domestic industries is \$326.55 thousand, at a 7 percent discount over 10 years. The projected additional annualized cost to these domestic industries is \$317.78 thousand, at a 3 percent discount over 10 years.

¹⁹ FDA March 2011 Labeling Cost Model.

At a 7-percent discount rate over 10 years, the projected additional annualized average net direct cost of the final rule provisions to the Siluriformes fish and Siluriformes food products domestic supply-chain industries is \$0.0008 (\$ 326.55 thousand/388,000 thousand pounds) per pound of aggregate Siluriformes fish and Siluriformes fish food products processed, on average yearly, in 2011, 2012, and 2013 (the last 3-year average of domestic and imported Siluriformes fish products), according to the USDA National Agricultural Statistics Service (NASS),^{20, 21, 22} and the import records of the U.S. Department of Homeland Security (DHS).²³ The additional average net direct cost of the provisions to the Siluriformes fish food products domestic industry compares to the average price received by domestic processors for domestic aggregate catfish (of the order Siluriformes) food products that was \$3.04 per pound, in 2013, according to the NASS publication (2013).

²⁰ Source: Catfish Processing Reports, NASS, USDA. 2011-2013.

²¹ Hanson, T and D. Sites. "2012 U.S. Catfish Database". Fisheries and Allied Aquacultures Department Series No. 1. Alabama Agricultural Experiment Station. Auburn University. Auburn, Alabama. March 2013. Sources: USDA National Agricultural Statistics Service (NASS) and Mississippi Agricultural Statistics Service (MASS).

²² Hanson, T and D. Sites. "2013 U.S. Catfish Database". Fisheries and Allied Aquacultures Department Series No. 1. Alabama Agricultural Experiment Station. Auburn University. Auburn, Alabama. April 2014. Sources: USDA National Agricultural Statistics Service (NASS) and Mississippi Agricultural Statistics Service (MASS).

²³ U.S. Department of Homeland Security (DHS) CBP import records of 2009 through 2013.

These additional regulatory costs compare to an estimated direct cost of about \$0.01 per pound of meat and poultry associated with the Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) rule of 1996.²⁴

²⁴ M. Ollinger, V. Mueller. 2003. Managing for Safer Food: The Economics of Sanitation and Process Controls in Meat and Poultry Establishments. Agricultural Economics Report 817. Economics Research Service, U.S. Department of Agriculture. Washington, D.C.

Table 3. Summary, projected additional average direct costs^{a b} to the domestic industry of the final rule measures.

New Measure	One-Time	Recurring (Savings)	Annualized Total Costs (Savings)	
			7 percent	3 percent
Industry Costs				
Sanitation SOPs	-	-	\$42,283	\$42,122
HACCP Plans – Validation	-	-	\$160,435	\$156,512
Pre-Harvest Actions - for Producers	\$0	\$60,971	\$60,971	\$60,971
Pre-Harvest Actions - for Haulers	\$86,400	\$18,355	\$29,851	\$28,189
Labels	\$131,670	\$13,398	\$30,918	\$28,384
Government Office Space and Equipment	\$16,500	\$7,200	\$9,396	\$9,078
Re-inspection at Import Establishments	\$8,910	\$27,477	\$28,663	\$28,492
Other - Reduced Payments	\$0	(\$35,970)	(\$35,970)	(\$35,970)
Sub-Total Industries Costs			\$326,548	\$317,777
Agency Costs:				
Additional Costs to FSIS Inspection	-	-	\$2,604,402	\$2,587,217
Reduced Costs to FDA		\$150,000	(\$150,000)	(\$150,000)
Reduced Costs to Commerce Dept NOAA NMFS		(\$1,340,000)	(\$1,340,000)	(\$1,340,000)
Sub-Total Agency Additional Costs			\$1,114,402	\$1,097,217
Total Net Costs			\$1,440,949	\$1,414,995

- a. Numbers in the table are rounded. Therefore, a total may not equal the sum of its parts
- b. Because the fish covered by this rulemaking present a new area of inspection for FSIS, there is a potential for the costs that the Agency is projecting to change during implementation. While FSIS believes that it can absorb at least some of the work for processing plants within existing patrol assignments, FSIS will not be able to completely validate this judgment until inspectors begin performing the inspections, and the agency is able to evaluate the workload that results. The Agency will not be able to make this final assessment until completion of the implementation phase.

F. Costs to Foreign Entities

1. Foreign Governments

In order for a foreign establishment to be eligible to export Siluriformes fish products to the United States, FSIS must first determine if the regulatory system under which the foreign establishment operates is equivalent to the United States regulatory system. FSIS used U.S. Customs and Border Protection entry data from the period of January 1, 2009 to December 31, 2013²⁵ to assess the number of countries currently exporting Siluriformes products to the United States. During that time period, 35 countries exported Siluriformes products to the United States. Of those, 26 registered fewer than 15 entries into the United States during that same period. The remaining nine countries (Table AA) registered between 30 and 24,474 shipments.

²⁵ Customs and Border Protection, Data pulled for OPPD by OFO/Recall Management and Technical Analysis Staff on February 18, 2014.

Table AA. Total Number of Shipments to the United States, Select Trading Partners, CY 2009 - 2013.						
Country of Origin	2009	2010	2011	2012	2013	Total # Shipments
CAMBODIA	125	53	33	3		214
CANADA	265	232	232	205	151	1,085
CHINA	538	434	269	200	353	1,794
INDONESIA	19	8	3			30
MALAYSIA	24	12	2	3	1	42
MEXICO	33	30	7	9	1	80
SPAIN	13	17	23	8		61
THAILAND	349	204	89	44	48	734
VIETNAM	2,603	3,094	5,480	6,741	6,556	24,474

The cost to a country of maintaining an equivalent inspection system as a result of any incremental change to its existing regulatory framework is likely to be minimal for several reasons. First, several of the governments currently exporting to the United States maintain a meat or poultry inspection system equivalent to that of the United States and are therefore aware of FSIS requirements.²⁶ Second, many foreign governments maintain inspection systems similar to that required by the FSIS in order to have access to other markets, e.g. European

²⁶ At present Canada, China, Mexico, and Spain have equivalent status for at least one FSIS regulated product.

Union²⁷ and Canadian markets²⁸. Third, FSIS has outlined a plan for phased implementation to mitigate disruptions. Finally, FSIS and FDA have established a Memorandum of Understanding²⁹ to assist our trading partners with the transition.

2. Foreign Establishments

Due to limitations in the data, FSIS ability to estimate the number of manufacturers shipping Siluriformes products to the United States is limited. In order to assess the impact on foreign establishments, FSIS queried the U.S. Customs and Border Protection, FDA, and NOAA for data related to the number of manufacturers currently exporting Siluriformes products to the United States. Based on the previously cited U.S. Customs and Border Protection entry data, there are an estimated 314 manufactures from the nine countries mentioned above that export Siluriformes products to the United States³⁰.

However, it is unclear from the data source mentioned

²⁷ The EU has approved importation of fish products from Vietnam, China, Canada, Thailand, Mexico, Spain, Malaysia, and Indonesia. This approval was granted after each country and its competent authority were evaluated for meeting specific requirements including residue monitoring and *Salmonella* spp. controls.

²⁸ Canada Food Inspection Agency, Import Information By Jurisdiction , Retrieved from <http://www.inspection.gc.ca/food/fish-and-seafood/imports/by-jurisdiction/eng/1373433337535/1373433338754>

²⁹ Memorandum of Understanding Between The Food Safety and Inspection Service United States Department of Agriculture And The Food and Drug Administration United States Department of Health and Human Services. Retrieved from <http://www.fsis.usda.gov/wps/wcm/connect/8675a5cb-7bca-4a8f-a563-7788adceb583/MOU-FSIS-FDA-Fish-Products.pdf?MOD=AJPERES>

³⁰ Customs and Border Protection, Data pulled for OPPD by OFO/Recall Management and Technical Analysis Staff on February 18, 2014.

above if these manufacturers exclusively ship Siluriformes products. Based on a FDA report to Congress,³¹ in 2008 there were approximately 14,900 foreign seafood firms registered to export product to the U.S. However, it is impossible to discern which of these firms deal with Siluriformes. While NOAA provided its December 2014 USDC Approved Establishments publication,³² due to data limitations it is impossible to determine which, if any, of these facilities export Siluriformes products to the United States. Even so, because foreign producers are currently meeting FDA standards, FSIS assumes that all establishments will continue to export Siluriformes product to the United State through the recognition of their respective national inspection systems and that the incremental costs to these establishments associated with this rule will be minimal. In addition, FSIS considered potential costs associated with reinspection at import facilities and has determined that it is not expected to cause an increase in spoilage because of the time needed

³¹ FDA Report to Congress. 20 November 2008. The Secretary's Report to Congress on Enhanced Aquaculture and Seafood Inspection.
<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm150954.htm>

³² NOAA USDC Approved Establishments. December 2014.
http://www.seafood.nmfs.noaa.gov/pdfs/participants_list14.pdf

to conduct the reinspection. The product arrives and is kept frozen.

G. Associated Costs to U.S. Consumers

FSIS has assumed that the transitional costs to foreign governments and producers are minimal. However, the Agency has also considered the possibility that any costs to these entities could be passed along to consumers. A review of the demand and supply literatures for Siluriformes yields ambiguous results. To start, given the numerous substitutes for Siluriformes filets, U.S. consumer demand for Siluriformes is expected to be elastic³³, indicating downward pressure on price. On the supply side, the United States International Trade Commission (USITC) determined the domestic supply of frozen Siluriformes filets to be elastic³⁴. Thus, any increase in price would be outpaced by an increase in domestic supply. This relationship puts downward pressure on price. Both volume-sold and retail-price data for 2005-2010 indicate that tilapia, pollock, and whiting, are competitive substitutes for both domestic and foreign Siluriformes. Competition for market share between these

³³ USITC. Certain Frozen Fish Fillets from Vietnam. Investigation No. 731-TA-1012ITC, 2009. Retrieved from http://www.usitc.gov/publications/701_731/pub4083.pdf

³⁴ Ibid.

substitutes is expected to put downward pressure on retail prices³⁵. Further, because foreign producers derive a competitive advantage through charging low prices, they are disincentivized from increasing the price they seek³⁶. On the supply side, the United States International Trade Commission (USITC) determined the domestic supply of frozen Siluriformes filets, a substitute for imported Siluriformes filets, to be elastic, indicating that domestic processors have the flexibility to response to a change in demand brought about by a change in imports³⁷. As such, any increase in price of imported Siluriformes would be curtailed by an increase in domestic supply. All else held equal, higher elasticity of supply leads to a greater portion of regulatory costs being borne by consumers (in the form of price increases) than by producers (in the form of decreases in profit). However, the combination of elastic demand and elastic supply suggests that any regulatory cost burdens will be shared between consumers and producers. Elastic demand, the presence of many substitutes, and the fact that foreign

³⁵ Dey, M.M., A.G. Rabbani, K. Singh, and C.R. Engle. 2014. Determinants of Retail Price and Sales Volume of Catfish Products in the United States: An Application of Retail Scanner Data, *Aquaculture Economics & Management*, 18:2, 120-148.

³⁶ Singh, K and M. M. Dey. 2011. International competitiveness of catfish in the U.S. market: A constant market share analysis. *Aquaculture Economics & Management*. 15:3, 214-229

³⁷ USITC. Certain Frozen Fish Fillets from Vietnam. Investigation No. 731-TA-1012ITC, 2009. Retrieved from http://www.usitc.gov/publications/701_731/pub4083.pdf

suppliers depend on low market prices for competitive advantage indicate that domestic Siluriformes prices are not expected to increase, whereas elastic supply would offset this increase to an undetermined degree.

H. Expected Budgetary Impacts on FSIS and Other Government Agencies

For the Government agencies, Table 3 shows the expected budgetary impacts that are the additional annualized average direct costs to FSIS and the reduced annualized average direct costs (i.e., a direct cost savings benefit) to FDA and the United States Department of Commerce's National Oceanic and Atmospheric Administration/National Marine Fisheries Service (USDC/NOAA/NMFS) with the implementation of the final rule.

The annualized cost to the Government Agencies is \$1,114.40 thousand, at a 7 percent discount over 10 years. The projected annualized cost to the government is \$1,097.22 thousand, at a 3 percent discount over 10 years.

I. Break-even Analysis

1. Possible Health Benefits -Assessment Break-even Analysis

FSIS conducted an assessment of the potential risk to human health of Siluriformes fish consumption, using the example of Salmonella spp. contamination. It focuses on exposure to Salmonella spp. because a broad hazard identification identified Salmonella spp. as one of the few potential hazards that there was sufficient data to assess in Siluriformes. The risk assessment provides different scenarios for the benefits that might result from an inspection system in Siluriformes similar to FSIS's inspection system for poultry.

In addition, FSIS is particularly interested in Salmonella spp. because, among foodborne pathogens in FSIS-regulated products, it is the most common cause of hospitalizations and fatalities, and therefore a serious concern in the United States.³⁸ We also note that there is evidence that at least one outbreak of human salmonellosis may have been related to Siluriformes consumption. FSIS acknowledges, however, that applying its empirical evidence describing the effectiveness of an FSIS

³⁸ CDC. CDC Estimates of foodborne illness in the United States. 2011. <http://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>

Batz, M. B., S. Hoffmann, and J. G. Morris, Jr. 2012. Ranking the disease burden of 14 pathogens in food sources in the United States using attribution data from outbreak investigations and expert elicitation. *Journal of Food Protection*. V75. 7. P1278-1291 and Scharff, R. L. 2012. Economic burden from health losses due to foodborne illness in the United States. *Journal of Food Protection*. V75. 1. P123-131

inspection program for Salmonella spp. control in another regulated species (i.e., poultry) carries with it significant limitations. Therefore, we use Salmonella spp. to present potential benefits in this break-even analysis, but we do not directly use the findings of the risk assessment to monetize the expected benefits of the FSIS *Siluriformes* inspection system.

Epidemiological evidence suggests that salmonellosis leads to both acute and chronic illnesses. The acute illness that accompanies salmonellosis generally causes gastrointestinal symptoms that can lead to lost productivity and medical expenses. In rare instances, salmonellosis may result in acute or chronic arthritis. Arthritis is characterized by limited mobility, pain and suffering, productivity losses, and medical expenditures. Finally, salmonellosis can result in death. The risk of death appears to be higher in the elderly, children, and people with compromised immune systems. FSIS has estimated the costs of these severity levels.

In summary, in Table 4 (below), for the final rule, FSIS projects the additional annualized average net direct cost to the domestic supply industry and the Government. The annualized cost to the industry and Government is

\$1,440.95 thousand, at a 7-percent discount rate over 10 years. At a 3-percent discount rate over 10 years, the annualized cost to the industry and Government is \$1,414.99 thousand.

Applying the methodology of the USDA Economic Research Service (ERS) in projecting a monetary value for each case, FSIS uses an annualized average direct cost of \$2,423 (in 2010 dollars) per new average case of salmonellosis.³⁹ Thus, under the final rule for all fish of the order Siluriformes, using the projected annualized cost of \$1,440.95 thousand (at a 7 percent discount rate over 10 years), and the estimated average direct cost of an average case of salmonellosis of \$2,423 (in 2010 dollars), if an average of 595 domestic cases were averted, the additional annualized average direct costs would be equal to the additional annualized average public health benefits (salmonellosis domestic cases averted) of the final rule. At a 3-percent discount rate over 10 years, using the projected annualized cost of \$1,414.99

³⁹ FSIS assumes that the average cost of illness is \$2,423 for a clinical case of salmonellosis, according to the USDA Economic Research Service (ERS) cost-calculator: the average direct cost of salmonellosis illnesses. (\$2,423 per case in 2010 dollars) was developed using the USDA, ERS Foodborne Illness Costs Calculator: Salmonella (June-2011). FSIS updated the ERS calculator to include Scallan case distribution for salmonellosis. Scallan, E., Hoekstra, R., Angulo, F., et.al. (2011). Foodborne Illness Acquired in the United States - Major Pathogens. *Emerging Infectious Diseases*, 17 (1), pp. 7-15.

thousand and the average direct cost of an average case of salmonellosis of \$2,423 (in 2010 dollars), if an average of about 584 cases were averted, the additional annualized average total net direct costs would be equal to the additional annualized average total public health benefits (salmonellosis illnesses averted) of the final rule. The assessment of the potential public health benefit of the final rule is from the FSIS Risk Assessment (December 2014). That illness estimate includes illnesses from consumption of both domestic and imported *Siluriformes*.

Because of data limitations, this RIA does not factor in the cost to foreign entities in a quantitative analysis. A qualitative analysis of market elasticities, foreign entities competitive advantages, and substitute goods, however, indicates that the cost to foreign entities is not expected to affect the break even analysis.

FSIS's primary cost estimate, used in the calculation above, includes zero costs to foreign establishments (and zero pass-through of foreign costs to U.S. consumers). If this estimate is correct, it is an indication that foreign establishments will not change their practices as a result of this rule, and thus there will be no health benefits to

U.S. consumers of imported Siluriformes; in other words, all the illness avoidance in the break-even result would need to be associated with consumption of domestic Siluriformes. If the zero foreign cost assumption is incorrect, then the level of illness avoidance that would be necessary for the rule to break even would be higher--and potentially much higher--than the estimates shown in this section. Of course, once the program is implemented, FSIS will have better data on true illness avoidance and on potential reductions in chemical residue hazards.

There is another reason to believe the break-even level of illness avoidance is higher than shown here. The actions assessed in the cost analysis are mostly related to knowledge of potential hazards, rather than the actual addressing of the hazards (for example, by discarding bad fish or taking a corrective action when an establishment that is newly monitoring a critical control point detects a deviation from an established critical limit). The latter is necessary for achieving health benefits and thus there are either costs--specifically, the costs of addressing hazards--currently omitted from the break-even calculation or the rule will not achieve the previously-calculated break-even point due to yielding negligible

benefits. There are also benefits to establishments and consumers that FSIS cannot quantify at this time. For example, we cannot quantify the gains in consumer confidence that may result from better quality product, more accurate labeling, or better control over pathogens or residues.

The assessment of the potential public health benefit of the final rule is from the FSIS Risk Assessment (December 2014). However, we note that under FSIS HACCP inspection as described in the risk assessment, Salmonella prevalence domestically has varied over time within meat and poultry product classes and among classes and establishment sizes. In a minority of cases, Salmonella prevalence has proved resistant to improvement. Therefore, the difference in Salmonella prevalence witnessed between the 1994-95 and 2007-08 microbiological baselines for broilers may not be indicative of the future trends in the microbiological quality of catfish, and substantial time and adaptations may be required before improvements are realized. However, even if the estimated public health benefits do not achieve the break-even point, FSIS inspection of Siluriformes is mandated by law and non-discretionary.

Table 4. Projected Summary Additional Annualized Average Net Direct Costs and Break-Even Assessment

Affected Sectors of the domestic economy	Additional annualized cost, over 10 years, discounted \$thousands		Assessment of Salmonellosis Illnesses Reduced Needed to Break Even on Annualized Costs, over 10 years and discounted -in cases averted annually	
	7 percent	3 percent	7 percent	3 percent
Siluriformes Fish Industry	\$ 326.55	\$ 317.78	135	131
Federal Government Agencies	\$ 1,114.40	\$ 1,097.22	460	453
Total	\$ 1,440.95	\$ 1,414.99	595	584

Footnotes: The FSIS estimate for the average cost of Salmonellosis illnesses (\$2,423 per case- in 2010 dollars) was developed using the USDA, ERS Foodborne Illness Costs Calculator: *Salmonella* (June-2011). FSIS updated the ERS calculator to include Scallan case distribution for salmonellosis. Scallan, E., Hoekstra, R., Angulo, F., et.al. (2011). Foodborne Illness Acquired in the United States – Major Pathogens. *Emerging Infectious Diseases*, 17 (1), pp.7-15.

2. Health Benefits - removing adulterated products from the market

Furthermore, as outlined in the hazard analysis section of the FSIS risk assessment, there is the potential for hazardous chemicals to be present in

Siluriformes. For example, in 2008, 9% of 150 and 2% of 53 imported catfish samples tested by FDA tested positive for malachite green and gentian violet, respectively. There is evidence that those chemical are mutagenic or carcinogenic, and FDA has banned the use of both of those chemicals as aquaculture drugs or pesticides. The FSIS National Residue Program will target chemical hazards (identified as hazards of concern in the hazard identification of the FSIS risk assessment) and conduct testing with the goal of removing adulterated products from the market. As a result, although the number of illnesses that could be avoided by removing Siluriformes adulterated with illegal or violative concentrations of chemicals could not be quantified—the fish consuming public may accrue additional unquantified public health benefits from the removal of those products from the market

J. Regulatory Flexibility Act Assessment

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601-602), the final rule will not have a significant impact on

a substantial number of small entities in the United States.

For the 842 affected entities of the U.S. domestic industry, we project an average of 624 fish farms and fish hatcheries; 18 establishments that slaughter and conduct primary processing of Siluriformes fish and Siluriformes fish products; and 200 facilities that are for (1) further/secondary processing-only of Siluriformes fish and Siluriformes fish products, (2) live-fish loaders/haulers/wholesalers of Siluriformes fish, (3) wholesalers/brokers/importers/exporters of Siluriformes fish, and (4) Siluriformes fish feed mills.

We based this on USDA NASS statistics (2013), Food and Drug Administration (FDA) (2014), import records of the U.S. Department of Homeland Security (DHS) (2009-2013),⁴⁰ Dun and Bradstreet (DNB) business database (2014), and the United States Census Bureau Economic Census (2012). See Table 5 for the details. Most of these establishments or entities meet the Small Business Administration (SBA) size criteria for small businesses in the food manufacturing classification or other categories, in that they have 500 or fewer employees. The final rule

⁴⁰ U.S. Department of Homeland Security (DHS) Custom and Border Protection (CBP) import records of 2009 through 2013.

would affect a substantial number of these small entities because the requirements would apply to all processing establishments in the Siluriformes fish and Siluriformes fish food processing industry that ship their products in interstate commerce and would to some extent pertain to fish-farming practices. As stated above in the cost section, the projected annualized cost to the domestic Siluriformes fish supply chain industries of the provisions of the final rule is \$0.0008 per pound of aggregate processed Siluriformes fish and Siluriformes fish food products. The additional average direct cost per pound of the provisions to the Siluriformes fish and Siluriformes fish food products domestic industry compares to the average wholesale net price per pound received by domestic processors for frozen and fresh catfish food products that was \$3.04 per pound, in 2013, according to the USDA, National Agricultural Statistical Service (NASS).⁴¹

Furthermore, this final rule will likely not have a significant effect on a substantial number of businesses that import Siluriformes fish and Siluriformes fish products. FSIS projects that those companies will

⁴¹ Wholesale price, gross value FOB plant. Source: Catfish Processing Reports, NASS, USDA. 2009-2013.

continue to import quantities of Siluriformes fish and Siluriformes fish products. Nevertheless, for the final rule, imported Siluriformes fish and Siluriformes fish products will be required to be inspected under a foreign system that is equivalent to that of the United States and be processed at establishments that the foreign inspection authority has certified as complying with United States requirements.

Table 5. Projected Number of Siluriformes fish and Siluriformes fish products entities in the domestic supply chain

Siluriformes fish Supply Chain Type (NAICS Code*)	No. of Establishments (FRIA)	% SBA Small
Slaughter and Primary Processors - Food Manufacturing (311712)	18	78%
Further/Secondary Processors-only - Food Manufacturing (311711)	10	100%
Producers- Farms, Ponds & Fish Hatcheries (112511)	624	100%
Feed Mills (311119)	14	86%
Loaders/Haulers(/Wholesalers) - Transporters Livestock Trucking (4842202)	11	100%
(Product) Wholesalers or Brokers, Importers and Exporters (424460)	165	100%
Total	842	

a. The Small Business Administration defines a small business in food manufacturing classification processing as an entity that is independently owned and operated, is organized for profit, is not dominant, and has 500 or fewer employees.

* North American Industry Classification System (NAICS) code, NAICS Association, 2002

Sources: National Agricultural Statistics Service (NASS)(2013), NASS Census of Agriculture 2014, US Food and Drug Administration(FDA)(2014), Dun and Bradstreet(DNB)(2014), US Census Bureau Economic Census (2012), Customs and Border Protection (CBP) import records of the U.S. Department of Homeland Security (DHS)(2009-2013), and catfish experts from the cooperative extension service and the catfish industry.

XIV. Paperwork Reduction Act

As provided by the 2014 Farm Bill (Section 12106(b)(3)), referencing Section 1601(c)(2)), FSIS is exempt from filing an information collection request under the Paper Work Reduction Act of 1995 (44 U.S.C. 3501, et. seq.)

XV. E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601 et seq.) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

XVI. Executive Order 12988, Civil Justice Reform

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

XVII. Expected Environmental Impact

Each USDA agency is required to comply with 7 CFR part 1b of the Departmental regulations, which supplements the National Environmental Policy Act (NEPA) regulations published by the Council on Environmental Quality. Under these regulations, actions of certain USDA agencies and agency units are categorically excluded from the preparation of an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) unless the agency head determines that an action may have a significant environmental effect (7 CFR 1b.4(b)). FSIS is among the agencies categorically excluded from the preparation of an EA or EIS (7 CFR 1b.4(b)(6)).

Currently, fish establishments are required to meet all local, State, and Federal environmental requirements. Under this final rule, fish establishments will still be required to meet all local, State and Federal environmental requirements. Thus, FSIS has determined that this final rule will not have significant individual or cumulative effect on the human health environment. Therefore, this regulatory action is appropriately subject to the categorical exclusion from the preparation of an EA or EIS provided under 7 CFR 1b.4(b)(6) of the USDA

regulations. In accordance with 7 CFR 1b.3(c), FSIS will continue to scrutinize its activities to determine continued eligibility for categorical exclusion.

XVIII. Executive Order 13175 Indian Tribal Governments

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

XIX. USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How to File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at

http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf, or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail:

U.S. Department of Agriculture
Director, Office of Adjudication
1400 Independence Avenue, SW
Washington, DC 20250-9410

Fax: (202) 690-7442

E-mail: program.intake@usda.gov

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

XX. Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this Federal Register publication on-line through the FSIS Web page located at:

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List of Subjects

9 CFR Part 300

Meat inspection.

9 CFR Part 441

Consumer protection standards, Meat and meat products, Poultry products, Fish and fish products.

9 CFR Part 530

Fish and fish products, Fish inspection.

9 CFR Part 531

Fish and fish products, Fish inspection.

9 CFR Part 532

Fish and fish products, Fish inspection, Reporting and recordkeeping requirements.

9 CFR Part 533

Fish and fish products, Fish inspection, Government employees.

9 CFR Part 534

Aquaculture, Fish and fish products, Fish inspection.

9 CFR Part 537

Fish and fish products, Fish inspection, Hazard Analysis and Critical Control Point (HACCP) Systems, Sanitation, Reporting and recordkeeping requirements.

9 CFR Part 539

Animal diseases, Fish and fish products, Fish inspection.

9 CFR Part 540

Fish and fish products, Fish inspection.

9 CFR Part 541

Fish and fish products, Fish inspection, Food labeling, Food packaging, Nutrition, Reporting and recordkeeping requirements, Signs and symbols.

9 CFR Part 544

Fish and fish products, Fish inspection, Food additives, Food packaging, Laboratories, Reporting and recordkeeping requirements.

9 CFR Part 548

Fish and fish products, Fish inspection, Food additives, Food packaging, Laboratories, Reporting and recordkeeping requirements, Signs and symbols.

9 CFR Part 550

Fish and fish products, Fish inspection, Reporting and recordkeeping requirements.

9 CFR Part 552

Fish and fish products, Fish inspection, Exports.

9 CFR Part 555

Fish and fish products, Fish inspection, Reporting and recordkeeping requirements, Transportation.

9 CFR Part 557

Fish and fish products, Fish inspection, Food labeling, Food packaging, Imports.

9 CFR Part 559

Fish and fish products, Fish inspection, Crime, Seizures and forfeitures.

9 CFR Part 560

Fish and fish products, Fish inspection, Intergovernmental relations.

9 CFR Part 561

Administrative practice and procedure, Fish and fish products, Fish inspection. Government employees.

For the reasons set forth in the preamble, 9 CFR chapter III is amended as follows:

Subchapter A - Agency Organization and Terminology;
Mandatory Meat and Poultry Products Inspection and
Voluntary Inspection and Certification

PART 300 -- AGENCY MISSION AND ORGANIZATION

1. The authority citation for part 300 continues to read as follows:

Authority: 21 U.S.C. 450-471, 601-695, 1031-1056; 7 U.S.C. 138-138i, 450, 1621-1627, 1901-1906; 7 CFR 2.7, 2.18, 2.53.

2. Section 300.3(a) is revised as follows:

§300.3 FSIS organization.

(a) General. The organization of FSIS reflects the Agency's primary regulatory responsibilities: implementation of the FMIA, including fish of the order Siluriformes, the PPIA, and the EPIA. FSIS implements the inspection provisions of the FMIA, the PPIA, and the EPIA through its field structure.

* * * * *

SUBCHAPTER E—REGULATORY REQUIREMENTS UNDER THE FEDERAL MEAT INSPECTION ACT AND THE POULTRY PRODUCTS INSPECTION ACT

PART 441 – CONSUMER PROTECTION STANDARDS: RAW PRODUCTS

3. The authority citation for part 441 continues to read as follows:

Authority: 21 U.S.C. 451-470, 601-695; 7 U.S.C. 450, 1901-1906; 7 CFR 2.18, 2.53

4. In §441.10, remove the term "Raw livestock and poultry" and add in its place the term "Raw livestock, poultry, and fish" at the beginning of the first sentence of paragraph (a) and at the beginning of the first sentence of paragraph (b).

5. A new Subchapter F, consisting of Parts 530 to 561, is added to Chapter III to read as follows:

Subchapter F - Mandatory Inspection of Fish of the Order
Siluriformes and Products of Such Fish

Part

530 - General Requirements; Definitions

531 - Definitions

532 - Requirements for Inspection

533 - Separation of Establishment; Facilities for
Inspection; Facilities for Program Employees; Other
Required Facilities

534 - Pre-Harvest Standards and Transportation to
Processing Establishment

537 -- Sanitation Requirements and Hazard Analysis and
Critical Control Points Systems; Notification Regarding
Adulterated or Misbranded Products

539 -- Mandatory Dispositions; Performance Standards
Respecting Physical, Chemical, or Biological Contaminants

540 -- Handling and Disposal of Condemned and Other
Inedible Materials

541 -- Marks, Marking and Labeling Of Products and
Containers

544 -- Food Ingredients Permitted

548 -- Preparation of Products

549 -- [Reserved]

550 -- Records Required to be Kept

552 - Exports

555 -- Transportation of Fish Products in Commerce

557 -- Importation

559 -- Detention, Seizure, Condemnation

560 -- State-Federal, Federal-State Cooperative
Agreements; State Designations

561 -- Rules of Practice

Subchapter F - Mandatory Inspection of Fish of the Order
Siluriformes and Products of Such Fish

PART 530 - GENERAL REQUIREMENTS; DEFINITIONS

Sec.

530.1 General.

530.2 FSIS organization for fish inspection.

530.3 Access to establishments.

Authority: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C.

601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

§530.1 General.

(a) The regulations in this subchapter provide for the inspection of Siluriformes fish and fish products. The inspection and regulations are intended to prevent the sale, transportation, offer for sale or transportation, or receipt for transportation, in commerce of any fish or fish product that is capable of use as human food and is adulterated or misbranded at the time of the sale,

transportation, offer for sale or transportation, or receipt for transportation.

(b) Fish as defined in this subchapter are amenable to the Act, including, as the Administrator may determine, to provisions of the Act in which other amenable species are named, except where the Act specifically excludes the provisions from applicability to fish.

§530.2 FSIS organization for inspection of fish and fish products.

The Food Safety and Inspection Service, U.S. Department of Agriculture, administers an inspection program for fish and fish products. The organization of FSIS and the principal offices of FSIS and their functions are described, and organizational terms defined, in 9 CFR part 300, subchapter A of this chapter. Section 300.3 lists the FSIS district offices and the geographic areas of the districts.

§530.3 Access to establishments.

The provisions of 9 CFR 300.6 apply to fish processing establishments and related industries as they do to other establishments subject to the FMIA.

PART 531 - DEFINITIONS

Sec.

531.1 Definitions.

Authority: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

§ 531.1 Definitions.

As used in this subchapter, unless otherwise required by the context, the following terms shall be construed, respectively, to mean:

Act. The Federal Meat Inspection Act, as amended, (34 Stat. 1260, as amended, 81 Stat. 584, 84 Stat. 438, 92 Stat. 1069, 106 Stat. 4499, 119 Stat. 2166, 122 Stat. 1369, 122 Stat. 2130, 21 U.S.C., sec. 601 et seq.).

Adulterated. This term applies to any carcass, part thereof, fish or fish food product under one or more of the following circumstances:

(1) If it bears or contains any such poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health;

(2) (i) If it bears or contains (by reason of administration of any substance to the live animal or

otherwise) any added poisonous or added deleterious substance (other than one which is:

(A) A pesticide chemical in or on a raw agricultural commodity;

(B) A food additive; or

(C) A color additive which may, in the judgment of the Administrator, make such article unfit for human food;

(ii) If it is, in whole or in part, a raw agricultural commodity and such commodity bears or contains a pesticide chemical which is unsafe within the meaning of section 408 of the Federal Food, Drug, and Cosmetic Act;

(iii) If it bears or contains any food additive which is unsafe within the meaning of section 409 of the Federal Food, Drug, and Cosmetic Act;

(iv) If it bears or contains any color additive which is unsafe within the meaning of section 706 of the Federal Food, Drug, and Cosmetic Act: Provided, That an article which is not deemed adulterated under paragraphs (2) (ii), (iii), or (iv) of this definition shall nevertheless be deemed adulterated if use of the pesticide chemical food additive, or color additive in or on such article is prohibited by the regulations in this subchapter in official establishments;

(3) If it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food;

(4) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(5) If it is, in whole or in part, the product of an animal which has died otherwise than by slaughter;

(6) If its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health;

(7) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act;

(8) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefore; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto

or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

Amenable species. A species that is, and whose products are, subject to the Act and regulations promulgated under the Act, except as the Act may provide.

Animal food. Any article intended for use as food for dogs, cats, or other animals, derived wholly, or in part, from the carcass or parts or products of the carcass of any amenable species, except that the term animal food as used herein does not include:

- (1) Processed dry animal food or
- (2) Feeds for amenable species manufactured from processed by products of amenable species.

Applicant. Any person who requests inspection service, exemption, or other authorization under the regulations.

Biological residue. Any substance, including metabolites, remaining in fish at time of slaughter or in any of their tissues after slaughter as the result of treatment or exposure of the fish to a pesticide, organic or inorganic compound, hormone, hormone like substance, anthelmintic, or other therapeutic or prophylactic agent.

Capable of use as human food. This term applies to any carcass or part or product of a carcass of any fish unless it is denatured or otherwise identified as required by §540.3 of this subchapter to deter its use as a human food, or it is naturally inedible by humans; e.g., barbels or fins in their natural state.

Carcass. All parts, including viscera, of any slaughtered livestock.

Commerce. Commerce between any State, any Territory, or the District of Columbia, and any place outside thereof; or within any Territory not organized with a legislative body, or the District of Columbia.

Consumer package. Any container in which a fish product is enclosed for the purpose of display and sale to household consumers.

Container. Any box, can, tin, cloth, plastic, or any other receptacle, wrapper, or cover.

Dead fish. The body of a fish that has died otherwise than by slaughter.

Dying or diseased fish. Fish affected by any of the conditions for which the fish are required to be condemned under part 539 or other regulations in this subchapter.

Edible. Intended for use as human food.

Farm-raised. Grown under controlled conditions, within an enclosed space, as on a farm.

Federal Food, Drug, and Cosmetic Act. The Act so entitled, approved June 25, 1938 (52 Stat. 1040), and Acts amendatory thereof or supplementary thereto.

Firm. Any partnership, association, or other unincorporated business organization.

Fish. (1) For the purposes of this subchapter, any fish of the order Siluriformes, whether live or dead.

(2) The skeletal muscle tissue of fish. As applied to products of fish of the order Siluriformes, this term has a meaning comparable to that of "meat" in the meat inspection regulations (9 CFR 301.2).

Fish byproduct. Any fish part capable of use as human food, other than the skeletal muscle tissue, that has been derived from one or more fish.

Fish food product. Any article capable of use as human food that is made wholly or in part from any fish or part thereof; or any product that is made wholly or in part from any fish or part thereof, excepting those exempted from definition as a fish product by the Administrator in specific cases or by a regulation in this

subchapter; upon a determination that they contain fish ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the fish food industry, and provided that they comply with any requirements that are imposed in such cases or regulations as conditions of such exemptions to ensure that the fish meat or other portions of such carcasses contained in such articles are not adulterated, and that such articles are not represented as fish food products.

Fish product. Any fish or fish part; or any product that is made wholly or in part from any fish or fish part, except for those exempted from definition as a fish product by the Administrator in a regulation in this subchapter. Except where the context requires otherwise (e.g., in part 540 of this subchapter), this term is limited to articles capable of use as human food.

Further processing. Smoking, cooking, canning, curing, refining, or rendering in an official establishment of product previously prepared in official establishments.

Immediate container. The receptacle or other covering in which any product is directly contained or wholly or partially enclosed.

Inedible. Adulterated, uninspected, or not intended for use as human food.

"Inspected and passed" or "U.S. Inspected and Passed" or "U.S. Inspected and Passed by Department of Agriculture" (or any authorized abbreviation thereof).

This term means that the product so identified has been inspected and passed under the regulations in this subchapter, and at the time it was inspected, passed, and identified, it was found to be not adulterated.

Label. A display of written, printed, or graphic matter upon the immediate container (not including package liners) of any article.

Labeling. All labels and other written, printed, or graphic matter:

(1) Upon any article or any of its containers or wrappers, or

(2) Accompanying such article.

Misbranded. This term applies to any carcass, part thereof, fish or fish food product under one or more of the following circumstances:

(1) If its labeling is false or misleading in any particular;

(2) If it is offered for sale under the name of another food;

(3) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and immediately thereafter, the name of the food imitated;

(4) If its container is so made, formed, or filled as to be misleading;

(5) If in a package or other container unless it bears a label showing:

(i) The name and place of business of the manufacturer, packer, or distributor; and

(ii) An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; except as otherwise provided in part 317 of this subchapter with respect to the quantity of contents;

(6) If any word, statement, or other information required by or under authority of the Act to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and

in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) If it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by the regulations in part 319 of this subchapter unless:

(i) It conforms to such definition and standard, and

(ii) Its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

(8) If it purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by the regulations in part 319 of this subchapter, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard;

(9) If it is not subject to the provisions of paragraph (7)(ii) of this definition unless its label bears:

(i) The common or usual name of the food, if any there be, and

(ii) In case it is fabricated from two or more ingredients, the common or usual name of each such ingredient, except as otherwise provided in part 317 of this subchapter;

(10) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as is required by the regulations in part 317 of this subchapter.

(11) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears a label stating that fact; except as otherwise provided by the regulations in part 317 of this subchapter; or

(12) If it fails to bear, directly thereon or on its containers, when required by the regulations in part 316 or 317 of this subchapter, the inspection legend and, unrestricted by any of the foregoing, such other information as the Administrator may require in such regulations to assure that it will not have false or misleading labeling and that the public will be informed

of the manner of handling required to maintain the article in a wholesome condition.

Nonfood compound. Any substance proposed for use in official establishments, the intended use of which will not result, directly or indirectly, in the substance becoming a component or otherwise affecting the characteristics of fish food and fish products excluding labeling and packaging materials as covered in part 541 of this subchapter.

Official certificate. Any certificate prescribed by the regulations in this subchapter for issuance by an inspector or other person performing official functions under the Act.

Official device. Any device prescribed by the regulations in part 312 of this subchapter for use in applying any official mark.

Official establishment. Any slaughtering, cutting, boning, fish product canning, curing, smoking, salting, packing, rendering, or similar establishment at which inspection is maintained under the regulations in this subchapter.

Official import inspection establishment. This term means any establishment, other than an official

establishment as defined in this section, where inspections are authorized to be conducted as prescribed in part 557 of this subchapter.

Official inspection legend. Any symbol prescribed by the regulations in this subchapter showing that an article was inspected and passed in accordance with the Act.

Official mark. The official inspection legend or any other symbol prescribed by the regulations in this subchapter to identify the status of any article, fish, or fish product under the Act.

Packaging material. Any cloth, paper, plastic, metal, or other material used to form a container, wrapper, label, or cover for fish products.

Person. Any individual, firm, or corporation.

Pesticide chemical, food additive, color additive, raw agricultural commodity. These terms shall have the same meanings for purposes of the Act and the regulations in this subchapter as under the Federal, Drug, and Cosmetic Act.

Prepared. Slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.

Process authority. A person or organization with expert knowledge in fish production process control and

relevant regulations. This definition does not apply to §548.6 of this subchapter or to subpart G of part 318 of this chapter.

Process schedule. A written description of processing procedures, consisting of any number of specific, sequential operations directly under the control of the establishment employed in the manufacture of a specific product, including the control, monitoring, verification, validation, and corrective action activities associated with production. This definition does not apply to §548.6 of this subchapter or to subpart G of part 318 of this chapter.

Producer. Any person engaged in the business of growing farm-raised fish.

Product. Any carcass, fish, fish product, or fish food product, capable of use as human food.

Program. The organizational unit within the Department having the responsibility for carrying out the provisions of the Act.

Program employee. Any inspector or other individual employed by the Department or any cooperating agency who is authorized by the Secretary to do any work or perform any duty in connection with the Program.

Slaughter. With respect to fish, intentional killing under controlled conditions.

State. Any State of the United States or the Commonwealth of Puerto Rico.

Territory. Guam, the Virgin Islands of the United States, American Samoa, and any other territory or possession of the United States.

U.S. Condemned. This term means that the fish, part, or product of fish so identified was inspected and found to be adulterated and is condemned.

U.S. Detained. This term applies to fish, fish products, and other articles which are held in official custody in accordance with section 402 of the Act (21 U.S.C. 672), pending disposal as provided in the same section 402.

U.S. Retained. This term means that the fish, part, or product of fish so identified is held for further examination by an inspector at an official establishment to determine its disposal.

United States. The States, the District of Columbia, and the Territories of the United States.

PART 532 - REQUIREMENTS FOR INSPECTION

Sec.

532.1 Establishments requiring inspection.

532.2 Application for inspection; information to be furnished; grant or refusal of Inspection; conditions for receiving inspection; official numbers and inspection; assignment and authorities of Program employees.

532.3 Exemption of retail operations.

532.4 Inspection at official establishments; relation to other authorities.

532.5 Exemption from definition of fish product of certain human food products containing fish.

Authority: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

§532.1 Establishments requiring inspection; other inspection.

(a) No establishment may process or prepare fish, fish parts, or fish products capable of use as human food, or sell, transport, or offer for sale or transportation in commerce any of these articles without inspection under these regulations, except as expressly exempted in §532.3.

(b) Inspection under the regulations is required at:

(1) Every establishment, except as provided in the regulation on exemption of retail operations (§532.3), in which any fish or fish products are wholly or in part,

processed for transportation or sale in commerce, as articles intended for use as human food.

(2) Every establishment, except as provided in the regulation on exemption of retail operations (§532.3), within any State or organized territory which is designated pursuant to section 301 of the Act (21 U.S.C. 661), at which any fish or fish products are processed for use as human food solely for distribution within that State or territory.

(3) Except as provided in the regulation on exemption of retail operations (§532.3), every establishment designated by the administrator under section 301 of the Act (21 U.S.C. 661) as one producing adulterated fish products which would clearly endanger the public health.

(4) Coverage of fish and fish products processed in official establishments. All fish and fish products prepared in an official establishment must be inspected, handled, processed, marked, and labeled as required by the regulations.

(5) Other inspection. Periodic inspections may be made of:

(i) The records of all persons engaged in the business of hatching, feeding, growing, or transporting fish between premises where fish are bred, hatcheries, and premises where fish are grown, and from these premises to processing establishments.

(ii) Exempted retail establishments to determine that those establishments are operating in accordance with these regulations.

§532.2 Application for inspection; information to be furnished; grant or refusal of Inspection; conditions for receiving inspection; official numbers and inspection; assignment and authorities of Program employees.

(a) Application for inspection is as required by 9 CFR 304.1.

(b) Information to be furnished is as required by 9 CFR 304.2(a), (b), and (c)(1). Conditions for receiving inspection, including having written Sanitation SOPs, HACCP plans and written recall procedures, are as required by 9 CFR 304.3.

(c) Official numbers; inauguration of inspection; withdrawal of inspection; reports of violation. The requirements for assignment of official numbers, inauguration of inspection, withdrawal of inspection, and

reports of violations at fish processing establishments are as required by part 305 of this chapter for meat establishments.

(d) Assignment and authorities of program employees.

The requirements concerning the assignment and authorities of Program employees at fish processing establishments are as required by parts 306 and 307 of this chapter with respect to Program employees at meat establishments.

§532.3 Exemption of retail operations.

(a) The exemption in 9 CFR 303.1(d) for operations of types traditionally and usually conducted at retail stores and restaurants applies with respect to fish products as it does with respect to products of other amenable species under the FMIA.

(b) The exemption also applies to the slaughtering of fish conducted at and by the operator of a retail store or restaurant, with respect to live fish purchased by a consumer at the retail store or restaurant, in accordance with the consumer's instructions.

(c) A retail quantity of fish or fish products sold to a household consumer is a normal retail quantity if it does not exceed 75 pounds and the quantity of fish or fish product sold by a retail supplier to a non-household

consumer is a normal retail quantity if it does not exceed 150 pounds in the aggregate.

§532.4 Inspection at official establishments; relation to other authorities.

(a) Requirements within the scope of the Act with respect to premises, facilities, and operations of any official establishment that are in addition to or different than those made under this subchapter may not be imposed by any State or local jurisdiction except that the State or local jurisdiction may impose recordkeeping and other requirements within the scope of §550.1 of this subchapter, if consistent with those requirements, with respect to the establishment.

(b) Labeling, packaging, or ingredient requirements in addition to or different than those made under this subchapter, the Federal Food, Drug, and Cosmetic Act and Fair Packaging and Labeling Act may not be imposed by any State or local jurisdiction with respect to any fish or fish products processed at any official establishment in accordance with the requirements under this subchapter and those Acts.

§532.5 Exemption from definition of fish product of certain human food products containing fish.

The following articles contain fish ingredients only in a relatively small proportion or historically have not been considered by consumers to be products of the fish food products industry. Therefore, the articles are exempted from the definition of "fish product" and the requirements of the Act and the regulations that apply to fish products, if they comply with the conditions specified in this section.

(a) Any human food product if:

(1) It contains less than 3 percent raw or 2 percent cooked fish;

(2) The fish ingredients used in the product were prepared under Federal inspection or were inspected under a foreign inspection system approved under §557.2 of this subchapter and imported in compliance with the Act and the regulations;

(3) The immediate container of the product bears a label which shows the name of the product in accordance with this section; and

(4) The product is not represented as a fish product. The percentage of cooked fish ingredients must be computed on the basis of the moist, deboned, cooked fish in the

ready-to-serve product when prepared according to the serving directions on the consumer package.

(b) A product exempted under this section will be deemed to be represented as a fish product if the term "fish" or a term representing a fish species that is covered by the definition of "fish" in part 531 of this subchapter is used in the product name of the product without appropriate qualification.

(c) A product exempted under this section is subject to the requirements of the Federal Food, Drug, and Cosmetic Act.

PART 533 - SEPARATION OF ESTABLISHMENT; FACILITIES FOR
INSPECTION; FACILITIES FOR PROGRAM EMPLOYEES; OTHER
REQUIRED FACILITIES

Sec.

533.1 Separation of establishments.

533.2 [Reserved]

533.3 Facilities for Program employees.

533.4 Other facilities and conditions to be provided.

533.5 Schedule of operations.

533.6 Overtime and holiday inspection service.

533.7 Basis of billing for overtime and holiday services.

Authority: 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

§533.1 Separation of establishments.

Each official establishment shall be separate and distinct from any unofficial establishment and from any other official establishment, except an establishment preparing products under the FMIA, the PPIA, or the EPIA, or under State fish inspection requirements and authorities that are deemed to be at least equal to those provided under the FMIA. Further, doorways, or other openings, may be permitted between establishments at the discretion of the Administrator and under such conditions as he may prescribe. An official establishment that is not separate and distinct from another official or unofficial establishment must ensure that no sanitary hazards are created by the lack of separation.

§533.2 [Reserved]

§533.3 Facilities for Program employees.

Office space, including necessary furnishings, light, heat, and janitor service, must be provided by official establishments, rent free, for the exclusive use for

official purposes of the inspector and other Program employees assigned thereto. The space set aside for this purpose shall meet with approval of the District Manager or the frontline supervisor and must be conveniently located, properly ventilated, and provided with lockers suitable for the protection and storage of Program supplies and with facilities suitable for Program employees to change clothing if such facilities are deemed necessary by the frontline supervisor. At the discretion of the Administrator, small establishments requiring the services of less than one full-time inspector need not furnish facilities for Program employees as prescribed in this section, where adequate facilities exist in a nearby convenient location. Laundry service for inspectors' outer work clothing must be provided by each establishment.

§533.4 Other facilities and conditions to be provided.

When required by the District Manager or the frontline supervisor, each official establishment must provide the following facilities and conditions, and such others as may be found to be essential to efficient conduct of inspection and maintenance of sanitary conditions:

(a) Sufficient light to be adequate for the proper conduct of inspection;

(b) Tables, benches, and other equipment on which inspection is to be performed, of such design, material, and construction as to enable Program employees to conduct their inspection in a ready, efficient and clean manner;

(c) Receptacles for holding and handling diseased carcasses and parts, so constructed as to be readily cleaned and to be marked in a conspicuous manner with the phrase "U.S. Condemned" in letters not less than 2 inches high, and, when required by the frontline supervisor, to be equipped in a way that allows the receptacles to be locked or sealed;

(d) Adequate arrangements, including liquid soap and cleansers, for cleansing and disinfecting hands, for sterilizing all implements used in handling diseased carcasses, for cleaning and sanitizing floors, and such other articles and places as may be contaminated by diseased carcasses or otherwise;

(e) Adequate facilities, including denaturing materials, for the proper disposal of condemned articles in accordance with the regulations in this subchapter;

(f) Docks and receiving rooms, to be designated by the operator of the official establishment, with the frontline supervisor, for the receipt and inspection of fish, fish products, or other products.

(g) Suitable lockers in which brands bearing the official inspection legend and other official devices (excluding labels) can be stored. Official certificates shall be kept when not in use in suitable file cabinets. All such lockers and file cabinets shall be equipped for sealing or locking with locks or seals to be supplied by the Department. The keys of such locks shall not leave the custody of Program employees.

§533.5 Schedule of operations.

The requirements governing the schedule of operations for fish processing establishments are as required by 9 CFR 307.4 for meat establishments.

§533.6 Overtime and holiday inspection service.

The requirements governing overtime and holiday inspection service in 9 CFR 307.5 apply to fish processing establishments.

§533.7 Basis of billing for overtime and holiday services.

The requirements for billing and overtime and holiday inspection services are as required by 9 CFR 307.6.

PART 534 - PRE-HARVEST STANDARDS AND TRANSPORTATION TO
PROCESSING ESTABLISHMENT

Sec.

534.1 General.

534.2 Water quality for food fish.

534.3 Standards for use of drugs in the raising of
fish.

534.4 Transportation to processing plant.

Authority: 21 U.S.C. 601-602, 606-622, 624-695; 7
CFR 2.7, 2.18, 2.53.

§534.1 General.

Fish that are harvested for use as human food must have grown and lived under conditions that will not render the fish or their products unsound, unwholesome, unhealthful, or otherwise unfit for human food.

§534.2 Water quality for food fish.

Farmers of fish should monitor the water in which the fish are raised for the presence of suspended solids, organic matter, nutrients, heavy metals, pesticides, fertilizers, and industrial chemicals that may contaminate fish. FSIS will collect samples of feed, fish, and water

from producers, at intervals to be determined by the Administrator, for the purpose of verifying that fish are being raised under conditions that will yield safe, wholesome products.

§534.3 Standards for use of drugs in the raising of fish.

New animal drugs that are the subject of an approved new animal drug application (NADA) or abbreviated new animal drug application (ANADA) under section 512 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360b), or a conditional approval under section 571 of the Act (21 U.S.C. 360ccc), or an investigational exemption under section 512(j) of the Act (21 U.S.C. 360b(j)) may be used in the raising of fish. New animal drugs approved under section 512 of the Act may be used in an extra-label manner if such use complies with section 512(a)(4) of the Act and FDA regulations found at 21 CFR part 530.

§534.4 Transportation to processing plant.

A vehicle used to transport fish from a producer's premises to a processing establishment must be equipped with vats or other containers for holding the fish. The vats or other containers must be maintained in a sanitary condition. Sufficient water and sufficient oxygen must be provided to the vats that hold the fish to ensure that

fish delivered to the processing establishment will not be adulterated. Any fish that are dead, dying, diseased, or contaminated with substances that may adulterate fish products are subject to condemnation at the official fish processing establishments.

PART 537 -- SANITATION REQUIREMENTS AND HAZARD ANALYSIS
AND CRITICAL CONTROL POINTS SYSTEMS; NOTIFICATION
REGARDING ADULTERATED OR MISBRANDED PRODUCTS

Sec.

537.1 Basic requirements.

537.2 Hazard analysis and HACCP plan.

537.3 Notification.

Authority: 21 U.S.C. 21 U.S.C. 601-602, 606-622,
624-695; 7 CFR 2.7, 2.18, 2.53.

§537.1 Basic requirements.

(a) (1) Any official establishment that prepares or processes fish or fish products for human food must comply with the requirements contained in 9 CFR parts 416, Sanitation and 417, Hazard Analysis and Critical Control Point (HACCP) Systems, except as otherwise provided in this subchapter.

(2) For the purposes of 9 CFR part 416, Sanitation; 9 CFR part 417, Hazard Analysis and Critical Control Point

(HACCP) Systems; and 9 CFR part 500, Rules of Practice, an "official establishment" or "establishment" includes a plant that prepares or processes fish or fish products.

§537.2 Hazard analysis and HACCP plan.

(a) A fish establishment's hazard analysis shall take into account the food safety hazards that can occur before, during, and after harvest.

(b) The failure of an establishment to develop and implement a hazard analysis and a HACCP plan that comply with this part or to operate in accordance with the requirements of 9 CFR Chapter III, Subchapter E, will render the products produced under these conditions adulterated.

§537.3 Notification.

Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded fish product received by or originating from the official establishment has entered commerce, in accordance with the requirements of 9 CFR part 418.

PART 539 -- MANDATORY DISPOSITIONS; PERFORMANCE STANDARDS
RESPECTING PHYSICAL, CHEMICAL, OR BIOLOGICAL CONTAMINANTS

Sec.

539.1 Disposal of diseased or otherwise adulterated fish carcasses and parts or fish products.

539.2 Physical, chemical, or biological contaminants.

Authority: 21 U.S.C. 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

§539.1 Disposal of diseased or otherwise adulterated fish carcasses and parts or fish products.

(a) (1) Carcasses or parts of fish affected by abscesses or lesions, zoonotic and non-zoonotic parasites such as cestodes, or such parasites as digenean trematodes, metacercaria (Bolbophorus spp.), yellow grubs (Clinostomum spp.), or white grubs (Hysteromorpha spp.) are subject to condemnation unless properly disposed of by the establishment to prevent their use as human food.

(2) Fish affected by Heterophyid intestinal flukes or Dictophymatidae nematodes are subject to condemnation unless properly disposed of by the establishment.

(b) Fish affected by diseases, including columnaris (infection by Flavobacterium columnare/Flexibacter columnaris) and enteric septicemia of fish (ESC), are subject to condemnation unless properly disposed of by the establishment to prevent their use as human food.

(c) Fish carcasses or parts or fish products that are found to be in a state of spoilage or decomposition are subject to condemnation unless properly disposed of by the establishment to prevent their use as human food.

(d) Fish with unusual gross deformities caused by disease or chemical contamination may not be used for human food.

§539.2 Physical, chemical, or biological contaminants.

(a) Fish and fish products that are contaminated with physical matter are subject to official retention and condemnation.

(b) Antibiotic or other drug residues in fish tissues must be within applicable tolerances in 21 CFR part 556 or within an applicable import tolerance established under 21 U.S.C. 360b(a)(6).

(c) Pesticide residues in fish tissues must be within applicable tolerances in 40 CFR part 180.

(d) Fish or fish products containing violative concentrations of drugs or other chemicals are subject to condemnation.

PART 540 -- HANDLING AND DISPOSAL OF CONDEMNED AND OTHER
INEDIBLE MATERIALS

Sec.

540.1 Dead fish.

540.2 Specimens for educational, research, and other nonfood purposes; permits.

540.3 Handling and disposal of condemned or other inedible materials.

Authority: 21 U.S.C. 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

§540.1 Dead fish.

(a) With the exception of dead fish that have died en route to an official establishment that have been received with live fish at the official establishment, and that are subject to sorting and disposal at the official establishment, no fish or part of the carcass of fish that died otherwise than by slaughter may be brought onto the premises of an official establishment without advance permission from the FSIS frontline supervisor.

(b) The official establishment shall maintain physical separation between slaughtered fish and the edible parts or products of slaughtered fish and any fish or parts of fish that have died otherwise than by slaughter. Fish or any parts of fish that have died otherwise than by slaughter shall be excluded from any

room or compartment in which edible product is prepared, handled, or stored.

§540.2 Specimens for educational, research, and other nonfood purposes; permits.

The requirements of 9 CFR 314.9 apply to the handling and release of specimens of condemned or other inedible fish materials.

§540.3 Handling and disposal of condemned or other inedible materials.

Condemned or other inedible fish and fish parts shall be separated from edible fish. If not disposed of on the premises of the establishment, the condemned and inedible fish parts shall be conveyed from the official establishment for disposition at a rendering plant, an animal feed manufacturing establishment, or at another establishment for other non-food use. If not decharacterized by use of approved denaturants or colorings, the inedible materials shall be enclosed in containers that are conspicuously marked to indicate that the contents are condemned or otherwise inedible. The materials may be shipped under company or official seal to a rendering facility or for other inedible processing.

PART 541 -- MARKS, MARKING AND LABELING OF PRODUCTS AND
CONTAINERS

Sec.

541.1 General.

541.2 Official marks and devices to identify
inspected and passed fish and fish products.

541.3 Official seals for transportation of products.

541.4 Official export inspection marks, devices, and
certificates.

541.5 Official detention marks and devices.

541.7 Labels required; supervision of a Program
employee.

Authority: 21 U.S.C. 21 U.S.C. 601-602, 606-622,
624-695; 7 CFR 2.7, 2.18, 2.53.

§541.1 General.

The marks, devices, and certificates prescribed or
referenced in this part are official marks, devices, and
certificates for the purposes of the Act respecting fish
and fish products. The marks, devices, and certificates
shall be used only in accordance with the regulations in
this part.

§541.2 Official marks and devices to identify inspected
and passed fish and fish products.

(a)(1) The official inspection legend required by this part must be shown on all labels for inspected and passed fish and fish products and must be in the following form prescribed in 9 CFR 312.2(b)(1) for inspected and passed products of cattle, sheep, swine, and goats, or in another form to be prescribed by the Administrator, except that it need not be of the size illustrated, if it is of a sufficient size and color to be conspicuously displayed, and readily legible, and in the same proportions of letter size and boldness are maintained as illustrated:



(2) The official inspection legend shall contain the words "U.S. Inspected and Passed" or an abbreviation of those words approved by the Administrator.

(b) This official mark must be applied by mechanical means and must not be applied by a hand stamp.

(c)(1) The official inspection legend, or the approved abbreviation of the legend, must be printed on consumer packages and other immediate containers of

inspected and passed fish products or on labels to be securely affixed to the containers of the products and may be printed or stenciled on the containers but must not be applied by rubber stamping.

(2) The official inspection legend may also be used for the purposes of marking shipping containers, band labels, and other articles with the approval of the Administrator.

(d) Whole gutted fish carcasses that have been inspected and passed in an official establishment and are intended for sale as whole gutted fish must be marked with the official inspection legend or properly packaged in an immediate container labeled with the official inspection legend and all other required labeling features, that will ensure that the fish carcasses are identified as "Inspected and Passed" and will not become misbranded while in commerce. The official inspection legend used for this purpose must be in the form illustrated below or in another form determined by the Administrator:



§541.3 Official seals for transportation of products.

The official mark for use in sealing railroad cars, cargo containers, or other means of conveyance as prescribed in part 555 of this subchapter must be the inscription and serial number shown in 9 CFR 312.5 or another official mark approved by the Administrator. Any seal approved by the Administrator for applying the official mark is an official device for the purposes of the Act. The seal must be attached to the means of conveyance only by a Program employee, who shall also affix a "Warning Tag" (Form MP-408-3 or similar official form).

§541.4 Official export inspection marks, devices, and certificates.

(a) The official export inspection mark for fish required by part 552 of this subchapter must be in the same form as that specified in 9 CFR 312.8(a) or otherwise as prescribed by the Administrator.

(b) The official export certificate for fish and fish products required by part 552 must be in the same form as that prescribed for meat and meat food products in 9 CFR 312.8(b) or otherwise as prescribed by the Administrator.

§541.5 Official detention marks and devices.

The official mark for shipments of articles and fish detained under this subchapter is the designation "U.S. Detained," and the official device for applying the mark is the official "U.S. Detained" tag (FSIS Form 8400-2) as prescribed in 9 CFR 329.2 or otherwise by the Administrator.

§541.7 Labels required; supervision of a Program employee.

(a) General labeling requirements. The requirements in part 317, subpart A, of this chapter, governing labels and labeling, safe-handling labeling, abbreviations of official marks, the use of approved labels, the labeling of products for foreign commerce, prohibited practices, the reuse of official inspection marks, filling of containers, relabeling of products, the storage and distribution of labels, and the requirements for packaging materials, apply to fish and fish products.

(b) A country of origin statement on the label of any fish "covered commodity" as defined in 7 CFR part 60, subpart A, that is sold by a "retailer," as defined in 7 CFR 60.124, must comply with the requirements of 7 CFR 60.200 and 60.300.

(c) The safe handling instructions required on labels of fish and fish products specified in paragraph (a) of this section shall replace statements that include the terms "meat" and "poultry" with the following:

(1) In the rationale statement, "This product was prepared from inspected and passed fish. Some food products may contain bacteria that could cause illness if the product is mishandled and cooked improperly. For your protection, follow these safe handling instructions." This statement shall be placed immediately after the heading and before the safe handling statements.

(2) In the labeling statements, "Keep raw fish separate from other foods. Wash working surfaces (including cutting boards), utensils, and hands after touching raw fish. (A graphic illustration of soapy hands under a faucet shall be displayed next to statement.)"

(d)(1) Labels and labeling of fish in the order Siluriformes and the products of those fish must bear the appropriate common or usual names of the fish. For example, among fish in the family Pangasiidae, the labels and labeling for fish of the species Pangasius bocourti must bear the term "basa"; for the species Pangasius

hypophthalmus or Pangasionodon hypophthalmus, "swai,"
"tra," or "sutchi."

(2) The labels and labeling only of fish and fish products within the family Ictaluridae may bear the term "catfish."

(e) The requirements in part 441 of this chapter, governing water retained from processing in raw meat and poultry, apply to retained water in fish. The requirements in part 442 of this chapter, governing quantity of contents labeling, the testing of scales, and the handling of product that is found to be out of compliance with net weight requirements, apply to fish and fish products.

(1) Packages of frozen or fresh-frozen fish carcasses or parts must be labeled to reflect 100-percent net weight after thawing. The de-glazed net weight must average 100 percent of the stated net weight of the frozen product when sampled and weighed according to the method prescribed in National Institute of Standards and Technology (NIST) Handbook 133 Chapter 2, Section 2.6.¹

(2) [Reserved]

¹ U.S. Department of Commerce. NIST Handbook 133: Checking the Net Contents of Packaged Goods, 2013. Washington, D.C.

(f) Nutrition labeling. The requirements for nutrition labeling of meat and meat food products in part 317, subpart B, of this chapter, also apply to the labeling of fish and fish food products.

(g) Label approval. The requirements for the label approval of meat and meat food products in part 412 of this chapter, also apply to the labeling of fish and fish products.

PART 544 -- FOOD INGREDIENTS PERMITTED

Sec.

544.1 Use of food ingredients.

Authority: 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

§544.1 Use of food ingredients.

(a) No fish product may bear or contain any food ingredient that would render it adulterated or misbranded or that is not approved in part 424 of this chapter, or in this part or elsewhere in this subchapter, or by the Administrator in specific cases.

(b) [Reserved]

PART 548 -- PREPARATION OF PRODUCTS

Sec.

548.1 Preparation of fish products.

548.2 Requirements concerning ingredients and other articles used in the preparation of fish products.

548.3 Samples of products, water, dyes, chemicals, etc. to be taken for examination.

548.4 [Reserved]

548.5 Ready-to-eat fish products.

548.6 Canning and canned products.

548.7 Use of new animal drugs.

548.8 Polluted water contamination at establishment.

548.9 Accreditation of non-Federal chemistry laboratories.

Authority: 7 U.S.C. 138f; 7 U.S.C. 450; 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

§548.1 Preparation of fish products.

(a) All processes used in preparing any fish product in official establishments shall be subject to inspection by Program employees unless such preparation is conducted as or consists of operations that are exempted from inspection under 9 CFR 303.1. No fixtures or appliances, such as tables, trucks, trays, tanks, vats, machines, implements, cans, or containers of any kind, shall be used unless they are of such materials and construction as will not contaminate or otherwise adulterate the product and

are clean and sanitary. All steps in the preparation of edible products shall be conducted carefully and with strict cleanliness in rooms or compartments separate from those used for inedible products.

(b) It shall be the responsibility of the operator of every official establishment to comply with the Act and the regulations in this subchapter. To carry out this responsibility effectively, the operator of the establishment shall institute appropriate measures to ensure the maintenance of the establishment and the preparation, marking, labeling, packaging and other handling of its products strictly in accordance with the sanitary and other requirements of this subchapter.

§548.2 Requirements concerning ingredients and other articles used in the preparation of fish products.

All ingredients and other articles used in the preparation of any fish product must be clean, sound, healthful, wholesome, and otherwise such as will not result in the product's being adulterated.

§548.3 Samples of products, water, dyes, chemicals, etc. to be taken for examination.

Samples of products, water, dyes, chemicals, preservatives, spices, or other articles in any official

establishment shall be taken, without cost to the Program, for examination, as often as may be deemed necessary for the efficient conduct of the inspection.

§548.4 [Reserved]

§548.5 Ready-to-eat fish products.

Ready-to-eat fish products are subject to the requirements in part 430 of this chapter.

§548.6 Canning and canned products.

The requirements for canning and canned products in 9 CFR part 318, subpart G (§§ 318.300-318.311) apply to fish products that are canned.

§548.7 Use of new animal drugs.

Edible tissues of fish with residues exceeding tolerance levels specified in 21 CFR part 556 or established in an import tolerance under 21 U.S.C. 360b(a)(6) are adulterated within the meaning of section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act because they bear or contain a new animal drug that is unsafe within the meaning of section 512 of the Federal Food, Drug, and Cosmetic Act.

§548.8 Polluted water contamination at establishment

In the event that there is polluted water (including but not limited to flood water) in an official

establishment, all products and ingredients for use in the preparation of the products that have been rendered adulterated by the water must be condemned. After the polluted water has receded from the establishment, the establishment must follow the cleaning and sanitizing procedures in §318.4 of this chapter.

§548.9 Accreditation of non-Federal chemistry laboratories.

A non-Federal analytical laboratory that has met the requirements for accreditation specified in 9 CFR part 439 and hence, at an establishment's discretion, may be used in lieu of an FSIS laboratory for analyzing official regulatory samples. Payment for the analysis of regulatory samples is to be made by the establishment using the accredited laboratory.

PART 549 -- [RESERVED]

PART 550 -- RECORDS REQUIRED TO BE KEPT

Sec.

550.1 Records required to be kept.

550.2 Place of maintenance of records.

550.3 Record retention period.

550.4 Access to and inspection of records, facilities and inventory; copying and sampling.

550.5 Registration.

550.6 Information and reports required from official establishment operators.

550.7 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.

Authority: 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

§550.1 Records required to be kept.

The requirements in 9 CFR 320.1 for records to be kept apply to persons that engage in businesses relating to fish and fish products as they do to persons that engage in businesses relating to the carcasses, parts, or products of other species amenable to the FMIA.

§550.2 Place of maintenance of records.

The requirements in 9 CFR 320.2 for the place where records are to be maintained apply in the keeping of records under this part.

§550.3 Record retention period.

The record retention requirements in 9 CFR 320.3 apply to records required to be kept under this part.

§550.4 Access to and inspection of records, facilities and inventory; copying and sampling.

The provisions of 9 CFR 320.4 apply to businesses dealing in fish and fish products.

§550.5 Registration.

The registration requirements in 9 CFR 320.5 apply to persons engaging in businesses, in or for commerce, relating to fish and fish products as they do to persons engaging in businesses relating to the carcasses, parts, and products, or any livestock, of other animal species that are amenable to the FMIA.

§550.6 Information and reports required from official establishment operators.

The information and reporting requirements in 9 CFR 320.6 for operators of official establishments apply with respect to fish and fish products as they do with respect to other species amenable to the FMIA.

§550.7 Reports by consignees of allegedly adulterated or misbranded products; sale or transportation as violations.

The requirements in 9 CFR 320.7 for reports by consignees of allegedly adulterated or misbranded products apply with respect to fish and fish products as they do with respect to products of other species amenable to the Act.

PART 552 - EXPORTS

Sec.

552.1 Affixing stamps and marking products for export; issuance of export certificates; clearance of vessels and transportation.

Authority: 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

§552.1 Affixing stamps and marking products for export; issuance of export certificates; clearance of vessels and transportation.

(a) The manner of affixing stamps and marking products for export is that prescribed in §322.1(a) of this chapter.

(b) The requirements for the issuance of export certificates are as prescribed in §322.2 of this chapter.

(c) The requirements for clearing vessels and other transportation vehicles are set out in §322.4 of this chapter.

PART 555 -- TRANSPORTATION OF FISH PRODUCTS IN COMMERCE

Sec.

555.1 Transportation of fish products.

555.2 Fish product transported within the United States as part of export movement.

555.3 Unmarked, inspected fish product transported under official seal between official establishments for further processing; certificate.

555.4 Handling of fish products that may have become adulterated.

555.5 Transportation of inedible fish product in commerce.

555.6 Certificates.

555.7 Official seals; forms, use, and breaking.

555.8 Loading or unloading of fish products in sealed transport conveyances.

555.9 Diverting of shipments.

555.10 Provisions inapplicable to specimens for laboratory examination, etc., or to naturally inedible articles.

555.11 Transportation and other transactions concerning dead, dying, or diseased fish, and fish or parts of fish that died otherwise than by slaughter.

555.12 Means of conveyance in which dead, dying, or diseased fish or parts of fish must be transported.

Authority: 7 U.S.C. 450; 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

§555.1 Transportation of fish products.

(a) No person may sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any fish or fish product that is capable of being used as human food and is adulterated or fails to bear an official inspection legend or is otherwise misbranded at the time of such sale, transportation, offer or receipt, except otherwise provided in this paragraph or in part 557 of this subchapter.

(b) No person, engaged in the business of buying, selling, freezing, storing, or transporting, in or for commerce, fish products capable of use as human food, or importing such articles, shall transport, offer for transportation, or receive for transportation, in commerce or in any State designated under §560.3 of this subchapter, any fish product which is capable of use as human food and is not wrapped, packaged, or otherwise enclosed to prevent adulteration by airborne contaminants, unless the railroad car, truck, or other means of conveyance in which the product is contained or transported is completely enclosed with tight fitting doors or other covers for all openings. In all cases, the means of conveyance shall be reasonably free of foreign matter (such as dust, dirt, rust, or other articles or

residues), and free of chemical residues, so that product placed therein will not become adulterated.

(c) Any cleaning compound, lye, soda solution, or other chemical used in cleaning the means of conveyance must be thoroughly removed from the means of conveyance prior to its use. Such means of conveyance onto which product is loaded, being loaded, or intended to be loaded, shall be subject to inspection by an inspector at any official establishment.

(d) The decision whether or not to inspect a means of conveyance in a specific case, and the type and extent of such inspection shall be at the Agency's discretion and shall be adequate to determine if fish product in such conveyance is, or when moved could become, adulterated.

(e) Circumstances of transport that can be reasonably anticipated shall be considered in making said determination. These include, but are not limited to, weather conditions, duration and distance of trip, nature of product covering, and effect of restowage at stops en route. Any means of conveyance found upon such inspection to be in such condition that fish product placed therein could become adulterated shall not be used until such condition which could cause adulteration is corrected.

Fish product placed in any means of conveyance that is found by the inspector to be in such condition that the fish product may have become adulterated shall be removed from the means of conveyance and handled in accordance with part 539 or §540.3 of this subchapter.

§555.2 Fish product transported within the United States as part of export movement.

When any shipment of any fish product is offered to any carrier for transportation within the United States as a part of an export movement, the same certificate shall be required as if the shipment were destined to a point within the United States.

§555.3 Unmarked, inspected fish product transported under official seal between official establishments for further processing; certificate.

The requirements governing transportation of fish product that has been inspected and passed, but not so marked, from one official establishment to another official establishment are the same as those in §325.5 of this chapter that apply to unmarked inspected meat products.

§555.4 Handling of fish products that may have become adulterated.

The provisions of §325.10 of this chapter regarding the handling of products that may have become adulterated or misbranded apply to fish and fish products.

§555.5 Transportation of inedible fish product in commerce.

The provisions in §325.11(e) of this chapter regarding the transportation of inedible livestock products apply to the transportation of inedible fish parts or products.

§555.6 Certificates.

The provisions in §325.14 of this chapter regarding the filing of original certificates of unmarked inspected meat products delivered to carriers applies with respect to fish and fish products.

§555.7 Official seals; forms, use, and breaking.

The official seals required by this part are those prescribed in §541.3 and §312.5 of this chapter.

§555.8 Loading or unloading of fish products in sealed transport conveyances.

The requirements in 9 CFR 325.17 governing the unloading of any meat or meat food product from an officially sealed railroad car, truck, or other means of conveyance containing any unmarked product or loading any

means of conveyance after the product leaves an official establishment are applicable to fish and fish products.

§555.9 Diverting of shipments

(a) Shipments of inspected and passed fish products that bear the inspection legend may be diverted from the original destination without a reinspection of the articles if the waybills, transfer bills, running slips, conductor's card, or other papers accompanying the shipments are marked, stamped, or have attached thereto signed statements in accordance with §325.15 of this chapter.

(b) In case of a wreck or similar extraordinary emergency, the Department seals on a railroad car or other means of conveyance containing any inspected and passed product may be broken by the carrier, and if necessary, the articles may be reloaded into another means of conveyance, or the shipment may be diverted from the original destination, without another shipper's certificate; but in all such cases the carrier must immediately report the facts by telephone or telegraph to the District Manager in the area in which the emergency occurs. The report must include the following information:

- (1) Nature of the emergency.
- (2) Place where seals were broken.
- (3) Original points of shipment and destination.
- (4) Number and initial of the original car or truck.
- (5) Number and initials of the car or truck into which the articles are reloaded.
- (6) New destination of the shipment.
- (7) Kind and amount of articles.

§555.10 Provisions inapplicable to specimens for laboratory examination, etc., or to naturally inedible articles.

The provisions of this part do not apply:

- (a) To specimens of product sent to or by the Department of Agriculture or divisions thereof in Washington, DC, or elsewhere, for laboratory examination, exhibition purposes, or other official use;
- (b) To material released for educational, research, and other nonfood purposes, as prescribed in §540.2 of this subchapter;
- (c) To tissues for use in preparing pharmaceutical, organotherapeutic, or technical products and not used for human food, as described in §540.2 of this subchapter;

(d) To material or specimens of product for laboratory examination, research, or other nonhuman food purposes, when authorized by the Administrator, and under conditions prescribed by him in specific cases; and

(e) To articles that are naturally inedible by humans.

§555.11 Transportation and other transactions concerning dead, dying, or diseased fish, and fish or parts of fish that died otherwise than by slaughter.

No person engaged in the business of buying, selling, or transporting in commerce, or importing any dead, dying, or diseased fish or parts of fish that died otherwise than by slaughter shall:

(a) Sell, transport, offer for sale or transportation, or receive for transportation, in commerce, any dead, dying, or diseased fish or parts of fish that died otherwise than by slaughter, unless the fish and parts are consigned and delivered, without avoidable delay, to establishments of animal food manufacturers, renderers, or collection stations that are registered as required by part 550 of this subchapter, or to official establishments that operate under Federal inspection, or to establishments that operate under a

State or Territorial inspection system approved by FSIS as one that imposes requirements at least equal to the Federal requirements for purposes of section 301(c) of the Act;

(b) Buy in commerce or import any dead, dying, or diseased fish or parts of fish that died otherwise than by slaughter, unless he is an animal food manufacturer or renderer and is registered as required by part 550 of this subchapter, or is the operator of an establishment inspected as required by paragraph (a) of this section and such fish or parts of fish are to be delivered to establishments eligible to receive them under paragraph (a) of this section;

(c) Unload en route to any establishment eligible to receive them under paragraph (a) of this section, any dead, dying, or diseased fish or parts of fish that died otherwise than by slaughter, which are transported in commerce or imported by any such person: Provided, That any such dead, dying, or diseased fish, or parts of fish may be unloaded from a means of conveyance en route where necessary in case of a wreck or otherwise extraordinary emergency, and may be reloaded into another means of conveyance; but in all such cases, the carrier must

immediately report the facts by telephone or other electrical or electronic means to the Office of Investigation, Enforcement and Audit, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

(d) Load into any means of conveyance containing any dead, dying, or diseased fish, or parts of fish that died otherwise than by slaughter, while in the course of importation or other transportation in commerce any fish or parts of fish not within the foregoing description or any other products or other commodities.

§555.12 Means of conveyance in which dead, dying, or diseased fish or parts of fish must be transported.

All vehicles and other means of conveyance used by persons subject to §555.11 for transporting in commerce or importing, any dead, dying, or diseased fish or parts of fish that died otherwise by slaughter must be leak proof and so constructed and equipped as to permit thorough cleaning and sanitizing. The means of conveyance used in conveying the fish or parts of fish must be cleaned and disinfected before being used in the transportation of any product intended for use as human food. The cleaning procedure must include the complete removal from the means

of conveyance of any fluid, parts, or product of dead, dying, or diseased fish and the thorough application of a disinfectant approved by the Administrator to the interior surfaces of the cargo space.

PART 557 -- IMPORTATION

Sec.

557.1 Definitions; application of provisions.

557.2 Eligibility of foreign countries for importation of fish and fish products into the United States.

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557.4 Imported fish and fish products; foreign certificates required.

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557.7 Products for importation; movement prior to inspection; handling; bond; assistance.

557.8 Import fish and fish products; equipment and means of conveyance used in handling to be maintained in sanitary condition.

557.9 [Reserved]

557.10 Samples; inspection of consignments; refusal of entry; marking.

557.11 Receipts to importers for import fish and fish products samples.

557.12 Foreign canned or packaged fish and fish products bearing trade labels; sampling and inspection.

557.13 Foreign fish and fish products offered for importation; reporting of findings to Customs.

557.14 Marking of fish products and labeling of immediate containers thereof for importation.

557.15 Outside containers of foreign products; marking and labeling; application of official inspection legend.

557.16 Small importations for importer's own consumption; requirements.

557.17 Returned U.S. inspected and marked fish and fish products.

557.18 Fish and fish products offered for entry and entered to be handled and transported as domestic; exception.

557.19 Specimens for laboratory examination and similar purposes.

557.20-557.23 [Reserved]

557.24 Appeals; how made.

557.25 Disposition procedures for fish and fish product condemned or ordered destroyed under import inspection.

§557.26 Official import inspection marks and devices.

Authority: 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

§557.1 Definitions; application of provisions.

(a) When used in this part, the following terms shall be construed to mean:

(1) Import. To bring within the territorial limits of the United States whether that arrival is accomplished by land, air, or water.

(2) Offer for entry. Presentation of the imported product by the importer to the Program for reinspection.

(3) Entry. The point at which imported product offered for entry receives reinspection and is marked with the official mark of inspection in accordance with §557.26 of this subchapter.

(b) The provisions of this part shall apply to fish and fish products that are capable of use as human food. Compliance with the conditions for importation of products under this part does not excuse the need for compliance with applicable requirements under other laws, including the provisions in part 94 of chapter I of this title.

§ 557.2 Eligibility of foreign countries for importation of fish and fish products into the United States.

(a) The requirements in 9 CFR 327.2(a)(1), (a)(2)(i), (a)(2)(ii)(C)-(I), (a)(2)(iii)-(iv), and (a)(3), for determining the acceptability of foreign meat inspection systems for the importation of meat and meat food products into the United States, apply in determining the acceptability of foreign fish inspection systems for the importation of fish and fish products into the United States. In determining the acceptability of these systems, the Agency will evaluate the manner in which they take into account the conditions under which fish are raised and transported to a processing establishment.

(b) (1) It has been determined that fish and fish products from the following countries covered by foreign inspection certificates of the country of origin as required by §557.4, are eligible under the regulations in this subchapter for entry into the United States after inspection and marking as required by the applicable provisions of this part: (None listed as of **[INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]**) .

(2) Persons interested in having the most recent list of eligible countries and establishments may contact the Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250.

§ 557.3 No fish or fish product to be imported without compliance with applicable regulations.

No fish or fish product offered for importation from any foreign country shall be admitted into the United States if it is adulterated or misbranded or does not comply with all the requirements of this subchapter that would apply to it if it were a domestic product.

§557.4 Imported fish and fish products; foreign certificates required.

(a) Except as provided in §557.16, each consignment containing any fish or fish products consigned to the United States from a foreign country must be accompanied by an electronic foreign inspection certificate or a paper foreign inspection certificate for fish and fish products. The certificate must have been issued by an official of the foreign government agency responsible for the inspection and certification.

(b) An official of the foreign government must certify that any fish or fish product described on any official certificate was produced in accordance with the regulatory requirements in §557.2.

(c) The electronic foreign inspection certification must be in English, be transmitted directly to FSIS before the product's arrival at the official import inspection establishment, and be available to import inspection personnel.

(d) The paper foreign inspection certificate must accompany each consignment; be submitted to import inspection personnel at the official import inspection establishment; be in English; bear the official seal of the foreign government responsible for the inspection of the product, and the name, title, and signature of the

official authorized to issue inspection certificates for products imported to the United States.

(e) The electronic foreign inspection certification and paper foreign inspection certificate must contain:

(1) The date;

(2) The foreign country of export and the producing foreign establishment number;

(3) The species used to produce the product and the source country and foreign establishment number, if the source materials originate from a country other than the exporting country;

(4) The product's description, including the process category, the product category, and the product group;

(5) The name and address of the importer or consignee;

(6) The name and address of the exporter or consignor;

(7) The number of units (pieces or containers) and the shipping or identification;

(8) The net weight of each lot;

(9) Any additional information the Administrator requests to determine whether the product is eligible to be imported into the United States.

§ 557.5 Importer to make application for inspection of fish and fish products for entry.

(a) Applicants must submit an import inspection application, to apply for the inspection of any product offered for entry. Applicants may apply for inspection using a paper or electronic application form.

(b) Import inspection applications for each consignment must be submitted, electronically or on paper, to FSIS in advance of the shipment's arrival at the official import establishment where the product will be reinspected, but no later than when the entry is filed with U.S. Customs and Border Protection.

(c) The provisions of this section do not apply to products that are exempted from inspection by §§557.16 and 557.17.

§557.6 Fish and fish products for importation; program inspection, time and place; application for approval of facilities as official import inspection establishment; refusal or withdrawal of approval; official numbers.

(a) (1) Except as provided in §§ 557.16 and 557.17, all fish and fish products offered for entry from any foreign country shall be reinspected by a Program

inspector before they shall be allowed entry into the United States.

(2) Every lot of product shall routinely be given visual inspection by a Program import inspector for appearance and condition, and checked for certification and label compliance.

(3) The electronic inspection system will be consulted for reinspection instructions. The electronic inspection system will assign reinspection levels and procedures based on established sampling plans and established product and plant history.

(4) When the inspector deems it necessary, the inspector may sample and inspect lots not designated by the electronic system.

(b) Fish and fish products required by this part to be inspected must be inspected only at an official establishment or at an official import inspection establishment approved by the Administrator as provided in this section.

(c) Owners or operators of establishments, other than official establishments, who want to have import inspections made at their establishments, shall apply to the Administrator for approval of their establishments for

such purpose. Application must be made on a form furnished by the Program, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC, 20250, and must include all information called for by that form.

(d) Approval for Federal import inspection must be in accordance with §§304.1 and 304.2 of this chapter. Also, before approval is granted, the establishment must have developed written Sanitation Standard Operating Procedures in accordance with part 416 of this chapter.

(e) Owners or operators of establishments at which import inspections of product are to be made shall furnish adequate sanitary facilities and equipment for examination of such product. The requirements of §§307.1, 307.2 (b), (d), (f), (h), (k), and (l) and 416.1 through 416.6 of this chapter shall apply as conditions for approval of establishments as official import inspection establishments to the same extent and in the same manner as they apply with respect to official establishments.

(f) The Administrator is authorized to approve any establishment as an official import inspection establishment, provided that an application has been filed in accordance with the requirements of paragraphs (c) and

(d) of this section and he determines that such establishment meets the requirements under paragraph (e) of this section. Any application for inspection under this section may be denied or refused in accordance with the rules of practice in part 500 of this chapter.

(g) Approval of an official import inspection establishment may be withdrawn in accordance with applicable rules of practice if it is determined that the sanitary conditions are such that the product is rendered adulterated, that such action is authorized by section 21(b) of the Federal Water Pollution Control Act, as amended (84 Stat. 91), or that the requirements of paragraph (e) of this section were not complied with. Approval may be withdrawn in accordance with section 401 of the Act and applicable rules of practice.

(h) A special official number shall be assigned to each official import inspection establishment. Such number shall be used to identify all products inspected and passed for entry at the establishment.

(i) A product examination must be made, as provided in paragraph (a) of this section, of a foreign fish or fish product, including defrosting if necessary to determine its condition. Inspection standards for foreign chilled

fresh or frozen fresh fish shall be the same as those used for domestic fish or fish products. Samples may be collected at no cost to FSIS and submitted to an FSIS laboratory for analysis (See §557.18).

(j) Imported canned products are required to be sound, healthful, properly labeled, wholesome, and otherwise not adulterated at the time the products are offered for importation into the United States. Provided other requirements of this part are met, the determination of the acceptability of the product and the condition of the containers shall be based on the results of an examination of a statistical sample drawn from the consignment as provided in paragraph (a) of this section. If the inspector determines, on the basis of the sample examination, that the product does not meet the requirements of the Act and regulations thereunder, the consignment shall be refused entry. However, a consignment rejected for container defects but otherwise acceptable may be reoffered for inspection under the following conditions:

(1) If the defective containers are not indicative of an unsafe and unstable product as determined by the Administrator;

(2) If the number and kinds of container defects found in the original sample do not exceed the limits specified for this purpose in FSIS guidelines; and

(3) If the defective containers in the consignment have been sorted out and exported or destroyed under the supervision of an inspector.

(k) Program inspectors or Customs officers at border or seaboard ports shall report the sealing of cars, trucks, or other means of conveyance, and the sealing or identification of containers of foreign product to Program personnel at points where such product is to be inspected.

(l) Representative samples of canned product designated by the Administrator in instructions to inspectors shall be incubated under supervision of such inspectors in accordance with §318.309 (d) (1) (ii), (d) (1) (iii), (d) (1) (iv) (c), (d) (1) (v), (d) (1) (vii) and (d) (1) (viii) of this chapter. The importer or his/her agent shall provide the necessary incubation facilities in accordance with §318.309(d) (1) (i) of this chapter.

(m) Sampling plans and acceptance levels as prescribed in paragraphs (j) and (l) of this section may be obtained, upon request, from the Office of Field Operations, Food

Safety and Inspection Service, U.S. Department of
Agriculture, Washington, DC 20250.

§557.7 Products for importation; movement prior to
inspection; handling; bond; assistance.

The requirements in 9 CFR 327.7 respecting the
movement or conveyance from any port, or delivery to the
consignee, of any product required to be inspected under
part 327, apply to fish and fish products.

§ 557.8 Import fish and fish products; equipment and
means of conveyance used in handling to be maintained in
sanitary condition.

Compartments of ocean vessels, railroad cars, and
other means of conveyance transporting any fish or fish
product to the United States, and all trucks, chutes,
platforms, racks, tables, tools, utensils, and all other
devices used in moving and handling any fish or fish
product offered for importation into the United States,
shall be maintained in a sanitary condition.

§557.9 [Reserved]

§557.10 Samples; inspection of consignments; refusal of
entry; marking.

The provisions in 9 CFR 327.10 governing the taking
of samples, the inspection of consignments, the refusal of

entry, and the controlled pre-stamping of shipments of meat and meat food products apply with respect to fish and fish products.

§557.11 Receipts to importers for import fish product samples.

FSIS will issue to importers official receipts for samples of foreign products collected for laboratory analysis, as provided in §327.11 of this chapter.

§557.12 Foreign canned or packaged fish and fish products bearing trade labels; sampling and inspection.

Foreign canned or packaged fish and fish products bearing on their immediate containers trade labels that have or have not been approved in accordance with the regulations in §541.7 of this subchapter are to be sampled and inspected in the same manner as provided by §327.12 of this chapter for foreign canned meat food products.

§557.13 Foreign fish and fish products offered for importation; reporting of findings to Customs.

Program inspectors are to report their findings as to any fish or fish products that have been inspected in accordance with this part in the same manner as that provided by §327.13 of this chapter for meat products. Fish and fish products that are refused entry are to be

handled in the same manner as provided by §327.13 of this chapter for meat products that are refused entry. Import personnel will identify to the Port Director of U.S. Customs and Border Protection and the Importer of record any products refused entry into the United States.

§557.14 Marking of fish and fish products and labeling of immediate containers thereof for importation.

The regulations in 9 CFR 327.14 governing the marking of meat and meat food products and the labeling of immediate containers of those products for importation apply with respect to fish and fish products.

§ 557.15 Outside containers of foreign products; marking and labeling; application of official inspection legend.

The requirements in 9 CFR 327.15 governing the marking and labeling of outside containers of meat and meat food products apply also with respect to fish and fish products.

§557.16 Small importations for importer's own consumption; requirements.

The exemption in 9 CFR 327.16 for small importations of meat or meat food products for the importer's own consumption applies with respect to fish or fish products.

§557.17 Returned U.S. inspected and marked fish and fish products.

U.S. inspected and passed and so marked fish products exported to and returned from foreign countries will be admitted into the United States without compliance with this part upon notification of and approval by the Assistant Administrator, Office of Field Operations, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, in specific cases.

§557.18 Fish or fish products offered for entry and entered to be handled and transported as domestic; exception.

The regulations in 9 CFR 327.18 governing the offer for entry into the United States of meat and meat food products apply with respect to fish and fish products. Products that fail to meet these regulatory requirements are subject to penalties as administered by the U.S. Port Director of Customs and Border Protection. Likewise, the products may be subject to detention and to being proceeded against as determined by the Administrator.

§557.19 Specimens for laboratory examination and similar purposes.

Importation of fish or fish product samples for trade show exhibition, laboratory examination, research, evaluative testing, trade show exhibition, or other scientific purposes are subject to the same conditions as imported meat or meat product specimens under §327.19 of this chapter.

§557.20-557.23 [Reserved]

§557.24 Appeals; how made.

An appeal from a decision of any Program employee is to be made as provided by 9 CFR 327.24.

§557.25 Disposition procedures for fish and fish products condemned or ordered destroyed under import inspection.

Disposition procedures for condemned fish or fish products ordered destroyed under import inspection are as those for carcasses, parts, meat, and meat food products under 9 CFR 327.25.

§557.26 Official import inspection marks and devices.

The official inspection legend and other marks to be applied to imported fish and fish products are as required by 9 CFR 327.26 for meat food products prepared from cattle, sheep, swine, and goats.

PART 559 -- DETENTION, SEIZURE, CONDEMNATION

Sec.

559.1 Fish and other articles subject to administrative detention.

559.2 Articles or fish subject to judicial seizure and condemnation.

559.3 Criminal offenses.

Authority: 7 U.S.C. 450; 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

§559.1 Fish and other articles subject to administrative detention.

The provisions of 9 CFR 329.1 through 329.5 governing the administrative detention of carcasses, parts, meat, and meat food products of livestock apply also with respect to the carcasses, parts, and products of fish.

§559.2 Articles or fish subject to judicial seizure and condemnation.

The provisions of 9 CFR 329.6 through 329.8 governing the judicial seizure and condemnation of carcasses, parts, meat, and meat food products of livestock apply also with respect to the carcasses, parts, and products of fish.

§559.3 Criminal offenses.

The criminal provisions of the Act apply with respect to the inspection of fish and fish products as they do

with respect to the inspection of other food products subject to the Act.

PART 560 -- STATE-FEDERAL, FEDERAL-STATE COOPERATIVE AGREEMENTS; STATE DESIGNATIONS

Sec.

560.1 Cooperation with States and Territories.

560.2 Cooperation of States in Federal programs.

560.3 Cooperation of States for the Interstate Shipment of Fish and Fish Products.

560.4 Designation of States under the Federal Meat Inspection Act.

Authority: 7 U.S.C. 450; 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

§560.1 Cooperation with States and Territories.

The provisions in §321.1 of this chapter authorizing the Administrator to cooperate with any State (including Puerto Rico) or any organized Territory in developing and administering a meat inspection program for the State or Territory apply with respect to fish and fish products inspection.

§560.2 Cooperation of States in Federal programs.

Under the "Talmadge-Aiken Act" of September 28, 1962 (7 U.S.C. 450), the Administrator is authorized to utilize

employees and facilities of any State in carrying out Federal functions under the FMIA, including functions relating to the inspection of fish and fish products. A cooperative program for this purpose is called a Federal-State program.

§560.3 Cooperation of States for the Interstate Shipment of Fish and Fish Products.

The provisions in §321.3 authorizing the Administrator to coordinate with States that have meat inspection programs as provided in §321.1 of this chapter to select certain establishments operating under these programs to participate in a cooperative program to ship products in interstate commerce apply with respect to fish and fish products inspection.

§560.4 Designation of States under the Federal Meat Inspection Act.

The requirements in part 331 of this chapter apply with respect to fish and fish products inspection, including:

(a) The requirements in 9 CFR 331.3 governing the designation of States for Federal inspection under section 301(c) of the Act (21 U.S.C. 661(c));

(b) The requirements in 9 CFR 331.5 governing the designation under section 301(c) of the Act of establishments whose operations would clearly endanger the public health; and

(c) The requirements in 9 CFR 331.6 governing the designation of States under section 205 of the Act.

PART 561 -- RULES OF PRACTICE

Sec.

561.1 Rules of practice governing inspection actions.

561.2 Rules of practice governing proceedings under the Federal Meat Inspection Act.

Authority: 7 U.S.C. 450; 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

§561.1 Rules of practice governing inspection actions.

The rules of practice in part 500 of this chapter, governing inspection actions taken by FSIS with respect to establishments and products, apply to actions taken with respect to fish slaughter, fish processing, fish, and fish products regulated under this subchapter.

§561.2 Rules of practice governing proceedings under the Federal Meat Inspection Act.

The procedures that the Agency must follow before reporting a violation of the Federal Meat Inspection Act for prosecution by the Department of Justice are given in part 335 of this chapter.

Done, at Washington, D.C.: November 18, 2015.

Alfred V. Almanza,
Acting Administrator.

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